CBP and Trade Automated Interface Requirements

FDA Supplemental Guidance for the Automated Commercial Environment/International Trade Data System (ACE/ITDS) Version 2.5

November 30, 2016

U.S. Customs and Border Protection

Contents

Change Log 7
General Introduction 17
FDA Overview 17
Legends 19
Field Requirements 19
Field Data Types 19
Required (Mandatory and/or Conditional)Data Elements for all FDA Commodities 20
FDA Commodities, Commodity Sub-Types & Corresponding Industry Codes 21
Biologics Commodity Data Elements and Values 22
Biologics Example 24
Record Identifier OI (Record Identifier) 25
Record Identifier PG01 (Record Identifier) 26
Record Identifier PG02 (Product Identifier) 28
Record Identifier PG04 (Product Constituent Element) 29
Record Identifier PG05 (Scientific Genus Names) 30
Record Identifier PG06 (Product Origin) 31
Record Identifier PG07 (Product Trade Names) 32
Record Identifier PG10 (Product Characteristics) 33
Record Identifier PG19 (Entity Data) 34
Record Identifier PG20 (Entity Address) 36
Record Identifier PG21 (Point of Contact) 37
Record Identifier PG23 (Affirmation of Compliance) 38
Record Identifier PG24 (Remarks) 42
Record Identifier PG25 (Product Condition) 43
Record Identifier PG26 (Product Packaging) 45
Record Identifier PG27 (Container Information) 49
Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry) 50
Record Identifier PG55 (Additional Entity Roles) 51
Record Identifier PG60 (Additional Information) 52
Record Identifier PG00 (Data Substitution) 53
Cosmetics Commodity Data Elements and Values 54
Cosmetics Example 55
Record Identifier OI (Record Identifier) 56
Record Identifier PG01 (PGA Identifier) 57
Record Identifier PG02 (Product Identifier) 58
Record Identifier PG06 (Product Origin) 59
Record Identifier PG07 (Product Trade Names) 60
Record Identifier PG10 (Product Characteristics) 61
Record Identifier PG19 (Entity Data) 62
Record Identifier PG20 (Entity Address) 64
Record Identifier PG21 (Point of Contact) 65
Record Identifier PG23 (Affirmation of Compliance) 66
Record Identifier PG24 (Remarks) 67
Record Identifier PG25 (Product Condition) 68
Record Identifier PG26 (Product Packaging) 70
Record Identifier PG27 (Container Information) 72
Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry) 73
Record Identifier PG55 (Additional Entity Roles) 74
Record Identifier PG60 (Additional Information) 75
Record Identifier PG00 (Data Substitution) 76
Drug Commodity Data Elements and Values 77
Drug Example 79
Record Identifier OI (Record Identifier) 80
Record Identifier PG01 (PGA Identifier) 81

Record Identifier PG02 (Product Identifier) ... 84
Record Identifier PG04 (Product Constituent Element) ... 86
Record Identifier PG06 (Product Origin) ... 89
Record Identifier PG07 (Product Trade Names) ... 90
Record Identifier PG10 (Product Characteristics) ... 91
Record Identifier PG19 (Entity Data) ... 92
Record Identifier PG20 (Entity Address) ... 94
Record Identifier PG21 (Point of Contact) ... 95
Record Identifier PG23 (Affirmation of Compliance) ... 96
Record Identifier PG24 (Remarks) ... 100
Record Identifier PG25 (Product Condition) ... 101
Record Identifier PG26 (Product Packaging) ... 103
Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry) ... 106
Record Identifier PG55 (Additional Entity Roles) ... 107
Record Identifier PG60 (Additional Information) ... 108
Record Identifier PG00 (Data Substitution) ... 115
Stand Alone Prior Notice Submission Data Elements and Values ... 109
Prior Notice Non-PGA Data Elements by Mode of Transportation (See Note) ... 109
Food Commodity Data Elements and Values ... 111
Prior Notice Example ... 113
Record Identifier OI (Record Identifier) ... 114
Record Identifier PG01 (PGA Identifier) ... 115
Record Identifier PG02 (Product Identifier) ... 117
Record Identifier PG06 (Product Origin) ... 118
Record Identifier PG10 (Product Characteristics) ... 120
Record Identifier PG13 (License Plate Issuer) ... 121
Record Identifier PG14 (License Plate Number) ... 122
Record Identifier PG19 (Entity Data) ... 123
Record Identifier PG20 (Entity Address) ... 127
Record Identifier PG21 (Point of Contact) ... 128
Record Identifier PG23 (Affirmation of Compliance) ... 130
Record Identifier PG24 (Remarks) ... 133
Record Identifier PG25 (Product Condition) ... 134
Record Identifier PG26 (Product Packaging) ... 135
Record Identifier PG27 (Container Information) ... 140
Record Identifier PG28 (Express Courier Tracking Number) ... 141
Record Identifier PG30 (Anticipated Arrival Info and Port of Arrival) ... 142
Record Identifier PG55 (Additional Roles) ... 143
Record Identifier PG60 (Additional Information) ... 144
Record Identifier PG00 (Data Substitution) ... 145
Food Commodity Combined Entry Submission - Data Elements and Values ... 146
Prior Notice Non-PGA Data Elements by Mode of Transportation (See Note) ... 148
Prior Notice Combined Entry Example ... 149
Record Identifier OI (Record Identifier) ... 150
Record Identifier PG01 (PGA Identifier) ... 151
Record Identifier PG02 (Product Identifier) ... 152
Record Identifier PG05 (Scientific Genus Names) ... 153
Record Identifier PG06 (Product Origin) ... 154
Record Identifier PG07 (Product Trade Names) ... 155
Record Identifier PG10 (Product Characteristics) ... 156
Record Identifier PG13 (License Plate Issuer) ... 157
Record Identifier PG14 (License Plate Number) ... 158
Record Identifier PG19 (Entity Data) ... 159
Record Identifier PG20 (Entity Address) ... 163
Record Identifier PG21 (Point of Contact) ... 164

Record Identifier PG23 (Affirmation of Compliance) ... 166
Record Identifier PG24 (Remarks) ... 170
Record Identifier PG25 (Product Condition) ... 171
Record Identifier PG26 (Product Packaging) ... 173
Record Identifier PG27 (Container Information) ... 178
Record Identifier PG28 Express Courier Tracking and Can Dimensions (Acidified and LACF) ... 179
Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry) ... 181
Record Identifier PG55 (Additional Entity Roles) ... 183
Record Identifier PG60 (Additional Information) ... 184
Record Identifier PG00 (Data Substitution) ... 185
Non-PN Food Commodity OR PN Requirements Previously Met - Data Elements and Values ... 186
Food Example ... 188
Record Identifier OI (Record Identifier) ... 189
Record Identifier PG01 (PGA Identifier) ... 190
Record Identifier PG02 (Product Identifier) ... 191
Record Identifier PG05 (Scientific Genus Names) ... 192
Record Identifier PG06 (Product Origin) ... 193
Record Identifier PG07 (Product Trade Names) ... 194
Record Identifier PG10 (Product Characteristics) ... 195
Record Identifier PG14 (PN Confirmation Number) ... 196
Record Identifier PG19 (Entity Data) ... 197
Record Identifier PG20 (Entity Address) ... 199
Record Identifier PG21 (Point of Contact) ... 200
Record Identifier PG23 (Affirmation of Compliance) ... 202
Record Identifier PG24 (Remarks) ... 205
Record Identifier PG25 (Product Condition) ... 206
Record Identifier PG26 (Product Packaging) ... 208
Record Identifier PG27 (Container Information) ... 213
Record Identifier PG28 (Can Dimensions – Acidified and LACF only) ... 214
Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry) ... 215
Record Identifier PG55 (Additional Entity Roles) ... 217
Record Identifier PG60 (Additional Information) ... 218
Record Identifier PG00 (Data Substitution) ... 219
Medical Devices Commodity Data Elements and Values ... 220
Medical Devices Example ... 222
Record Identifier OI (Record Identifier) ... 223
Record Identifier PG01 (PGA Identifier) ... 224
Record Identifier PG02 (Product Identifier) ... 226
Record Identifier PG06 (Product Origin) ... 227
Record Identifier PG07 (Product Trade Names) ... 228
Record Identifier PG10 (Product Characteristics) ... 229
Record Identifier PG19 (Entity Data) ... 230
Record Identifier PG20 (Entity Address) ... 232
Record Identifier PG21 (Point of Contact) ... 233
Record Identifier PG23 (Affirmation of Compliance) ... 234
Record Identifier PG24 (Remarks) ... 237
Record Identifier PG25 (Product Condition) ... 238
Record Identifier PG26 (Product Packaging) ... 240
Record Identifier PG27 (Container Information) ... 242
Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry) ... 242
Record Identifier PG55 (Additional Entity Roles) ... 244
Record Identifier PG60 (Additional Information) ... 245
Record Identifier PG00 (Data Substitution) ... 246
Tobacco Commodity Data Elements and Values ... 247
Tobacco Example ... 249

Record Identifier OI (Record Identifier) ... 250
Record Identifier PG01 (PGA Identifier) ... 251
Record Identifier PG02 (Product Identifier) ... 253
Record Identifier PG06 (Product Origin) ... 254
Record Identifier PG07 (Product Trade Names) ... 255
Record Identifier PG10 (Product Characteristics) ... 256
Record Identifier PG19 (Entity Data) ... 257
Record Identifier PG20 (Entity Address) ... 259
Record Identifier PG21 (Point of Contact) ... 260
Record Identifier PG23 (Affirmation of Compliance) ... 261
Record Identifier PG24 (Remarks) ... 263
Record Identifier PG25 (Product Condition) ... 264
Record Identifier PG26 (Product Packaging) ... 266
Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry) ... 269
Record Identifier PG55 (Additional Entity Roles) ... 270
Record Identifier PG60 (Additional Information) ... 271
Record Identifier PG00 (Data Substitution) ... 272
Radiation Emitting Products Commodity Data Elements and Values ... 273
Radiation Emitting Products Example ... 277
Record Identifier OI (Record Identifier) ... 278
Record Identifier PG01 (PGA Identifier) ... 279
Record Identifier PG02 (Product Identifier) ... 281
Record Identifier PG06 (Product Origin) ... 282
Record Identifier PG07 (Product Trade Names) ... 283
Record Identifier PG10 (Product Characteristics) ... 284
Record Identifier PG19 (Entity Data) ... 285
Record Identifier PG20 (Entity Address) ... 287
Record Identifier PG21 (Point of Contact) ... 288
Record Identifier PG23 (Affirmation of Compliance) ... 289
Record Identifier PG24 (Remarks) ... 293
Record Identifier PG25 (Product Condition) ... 294
Record Identifier PG26 (Product Packaging) ... 296
Record Identifier PG27 (Container Information) ... 298
Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry) ... 299
Record Identifier PG55 (Additional Entity Roles) ... 300
Record Identifier PG60 (Additional Information) ... 301
Record Identifier PG00 (Data Substitution) ... 302
Animal Drugs and Devices Commodity Data Elements and Values ... 303
Animal Drugs and Devices Example ... 305
Record Identifier OI (Record Identifier) ... 306
Record Identifier PG01 (PGA Identifier) ... 307
Record Identifier PG02 (Product Identifier) ... 309
Record Identifier PG04 (Product Constituent Element) ... 310
Record Identifier PG06 (Product Origin) ... 312
Record Identifier PG07 (Product Trade Names) ... 313
Record Identifier PG10 (Product Characteristics) ... 314
Record Identifier PG19 (Entity Data) ... 315
Record Identifier PG20 (Entity Address) ... 317
Record Identifier PG21 (Point of Contact) ... 318
Record Identifier PG23 (Affirmation of Compliance) ... 319
Record Identifier PG24 (Remarks) ... 322
Record Identifier PG25 (Product Condition) ... 323
Record Identifier PG26 (Product Packaging) ... 325
Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry) ... 327
Record Identifier PG55 (Additional Entity Roles) ... 328

Record Identifier PG60 (Additional Information) 329
Record Identifier PG00 (Data Substitution) 330
Appendix A: Use of PG10 Record 331
Appendix B: Food Facility Registration Exemption (FME) 332
Appendix C: Sample use of PG04 – Product Constituent Element 333
Appendix D: FDA Unit of Measurement Codes 334

Change Log

Date	Version No.	Description	Page Number
11/25/2014	1	Initial Version	129
1/02/2015	1.2	Updated all mandatory record types to match FDA business rules for CBP processing	Multiple pages
1/22/2015	1.3	Updates based on feedback from Trade in the 1/6 and 1/13 meetings; based on feedback from FDA's review of draft. Added Commodity type to Commodity sub-type mapping table.	Multiple pages
2/9/2015	1.4	Updates based on feedback from CDRH on Medical Devices and from CBP on all chapters; enforced consistence of same PG record types across commodities where there is no special handling from one commodity to another (example, PG06, PG20, PG21); updates based on feedback from Trade in the 1/20, 1/27 and 2/3 meeting.	Multiple pages
3/5/2015	1.6	Updates to Drugs chapter based on CBP's feedback; removed references to MID as the identifier for Trade; re-aligned the Processing Codes for Medical Devices	Multiple pages
3/19/2015	1.7	Removed references to ESS, SSN & TIN in PG19; Added 'DP' to PG19; the mandatory LOT# related fields in PG25 are now conditional; Improved rules for Item Type in PG02 record; Updates to Drugs chapter based on meeting with Philadelphia District Office; PG06 Notes are made consistent across all the commodities; added new Processing Codes for Radiation Emitting Products	Multiple pages
4/2/2015	1.8	For VME, PG07 is conditional; for Cosmetics, Cosmetic Registration Number (COS) is optional; for FOO, PG23 AoC Codes FCE/SID requirements are updated; for DRU PG23, REG is not required for PHN; updated the processing codes for drugs; PG25 – all values except PGA Line value are now optional for all commodities; PG27 record is now mandatory for PN but is optional for all commodities; PG26 is optional and PG29 is conditional for Drugs; added Appendix C for DRU;	Multiple pages
4/11/2015	1.9	Additional text added for PG30 record description based on the March 25th release of CATAIR; adjusted list of Intended Use Codes for PG01 in Radiation Emitting Products chapter per Amy Gomez, CDRH; changes to Drugs chapter PG01, PH02, PG04, PG19 and PG23 based on feedback from John Verbeten CDER; updates to Biologics chapter based on feedback from CBER;	Multiple pages
4/27/2015	2.0	Updated PG19 Entity identification criteria across all commodities; added subtypes to Tobacco; added PG04 to Tobacco and included feedback from CTP; includes CBER feedback in Biologics; added the new chapter on Device and Drug Combination Products chapter; added the new chapter for Prior Notice; included additional text to Food chapter to connect PN and Food chapters; updated the context of the PN and Food chapters to describe a stand-alone PN entry in the PN chapter and a combination entry (801a and 801m) in the Food chapter.	Multiple pages
5/12/2015	2.1	Updated **Drugs** chapter using 4/30/2015 & 5/8/2015 feedback from CDER; updated **Tobacco** chapter using 5/1/2015, 5/2/2015 & 5/7/2015 feedback from CTP; updated **Veterinary Medicine** chapter using 5/5/2015 & 5/8/2015 feedback from CVM; updated the **Biologics** chapter using 5/6/2015 feedback from CBER; updated Disclaimer in PG01 consistently across all the commodities; updated **Medical Devices** chapter using ACE ITDS Import Scenario Mapping19.xlsx from CDRH; updated **Cosmetics** chapter using feedback from CFSAN; updated **Radiation Emitting Products** chapter based on 5/7/2015 feedback from CDRH; updated **Prior Notice** chapter using 5/7/2015 feedback from DFDT;	Multiple pages
5/18/2015	2.1.1	Updates to PG30 to make mandatory for anticipated arrival time. Updated Prior Notice section to include data elements in the PE records. Various cosmetic and formatting updates	Multiple pages

Date	Version No.	Description	Page Number
6/12/2015	2.2	PG55 is not supported at this time for all FDA commodities; CBER AoC codes & business rules updated; PG25 - line value is required in all the PG25 records (repeated for multiple lot #); FDA product code = 7 characters; Added references to a new entity role code: FDC = FDA Consolidator; Valid list of port codes link added to PG30; Medical Devices - PG01 Intended Use Codes and sub-codes – updated; Radiation Emitting Products - PG01 Intended Use Codes and sub-codes – updated; PG20 is mandatory with additional notes for all commodities; dropped Remarks Code and clarified the Note in PG24 for all commodities; added Prior Notice Non-PGA Data Elements by Mode of Transportation to PN chapters; external sample file is referenced to provide samples for all commodities; included additional rules for entering PG19 entity role codes;	Multiple pages
8/18/2015	2.3.1	Updated **PN**-related chapters based on feedback from DFDT's FDA Supplemental Guide Release 2 2 DFDT Edits 07-02-15.docx, FDA Supplemental Guide Release 2 3 draft DFDT Edits 7-13-15.docx, FDA Supplemental Guide Release 2 3 with tracking DFDT Edits 7-20-15.docx and FDA Supplemental Guide Release 2 3 with tracking DFDT Edits 7-24-15.docx; updated **Medical Devices** and **Radiation Editing Products** chapters based on feedback from CDRH's FDA Supplemental Guide Release 2.2 abg.docx and final - FDA Supplemental Guide Release 2 3 with tracking - Device Chapter_abg + ja 150814abg.docx; changed the use of FD1 entity role code to DII for **CDRH** use; updated **PG26** across all commodities based on CBP's new descriptions of product packaging; updated **PG05-06-07-10** throughout the document to reference the most recent PG02; re-arranged the appendices and updated their references throughout the document; updated the validation criteria for **FEI** numbers across all commodities based on its current range of values in FDA's databases; clarified the text for **PG21** and **PG30** record across all commodities; clarified the references to PE10 and SE15 in conjunction with the PG Message Set in the **PN-related** chapters; in the **Drugs** chapter, added BLA to the scope of the AoC code DA (formerly NDA and AND); removed the use of Intended Use Codes for Food-related commodities and added logic depending on parts of product codes at group level; **PG01** is not repeatable for different Intended Use Codes; added the FDA Product Code structure to all commodities and included logic based on product codes in **Food-related** chapters; renamed veterinary medicine chapter to **Animal Drugs and Devices** per feedback from CVM and replaced references to veterinary medications by animal drugs in the entire document; updated **Tobacco** chapter based on feedback in Tobacco Data Elements - June 2015 exw jw jma.doc; updated **Biologics** chapter using feedback from FDA Supplemental Guide Release 2 3 CBER Edits.docx; updated Devices and Drug chapters in lieu of the **Device+Drug Combination** chapter before removing it; updated Devices and Biologics chapters in lieu of the **Device+Biologics Combination** chapter before removing it; added business rules for **PG24**; added Appendix E showing the use of PG04 both at Product-level and at Constituent Element-level and updated all commodities accordingly; added new AoC codes in the **Tobacco** chapter; added new UoM codes for **Drugs**;	Multiple pages
10/26/2015	2.3.2	**For all commodities:** Intended Use Description is optional; added Appendix F for the list of Unit of Measurement codes and included its reference in PG26 and PG29; PG29 is not supported by the FDA at this time; clarified the use of PG04 for multiple constituent elements under PG02 and corrected Appendix E accordingly; Line value in PG25 must be greater than zero; Quantity in PG26 must be greater than zero; PG19:Entity Number is optional; PG19:Entity Identification Code is Mandatory if PG19:Entity Number is entered; PG21:Telephone Number is 15X (alpha-numeric) to include global telephone numbers; added a national and an international telephone number as examples in PG21;	Multiple pages

Date	Version No.	Description	Page Number
		At least one PG21 record is required; **For specific commodities:** Government Agency Processing codes have changed for VME; reviewed and corrected the Intended Use Codes for BIO, DRU, DEV and VME – these changes will be in line with the next release of Schedule R by the CBP; corrected a typo in DRU:PG07; corrected Note3 text for Radiation Emitting Products:PG01; PG23:AoC codes are adjusted for BIO, DRU, DEV and VME; updated the mapping between the AoC codes and import scenarios for BIO and DRU chapters; PG01:Note3 for Cosmetics is deleted; PG04 is required for all DRU messages except PHN; Note5 is new in DRU:PG04; added the new AoC code PLR for drugs; added references to Carrier Name to PN-related chapters – the new AoC code CAN is added to PG23 for PN; Bulk (230.005) is not a valid IUC code for Food; all references to the AoC code PND are deleted in the Food chapters; clarified the rules for PG06, PG13 and PG14 for Food chapters; PG21:PK reference is added to all Food chapters; Food UoM tables are added to FOO chapters; PG28 is conditional for non-PN chapters – Note1 includes additional clarifications; for TOB:PG26, it is not required to enter 20 cigarettes in a pack – it may be entered if desired by the filer; IUC codes are optional for VME; the AoC code VMS is deleted from VME chapter; Clarified that ONE of MF/DFI/FDC is required for PN and only one of them is allowed; PG30 is used to collect Foreign Trade Zone (FTZ) information for the **FOO+PNC** chapter.	
10/29/2015	2.4	Corrected the footnotes in PG19 for Prior Notice chapters; clarified the percentage of constituent element in PG04 and added examples for DRU and VME chapters; AofC code is conditional for RAD chapter; new IUC codes are ordered to match the next release of Schedule R by CBP. Updated PG30 record for FOO+PNC chapter;	Multiple pages

Date	Version No.	Description	Page Number
3/31/2016	2.4.1	**For all commodities:** AoC Qualifier is 30 characters long; Sum of all PGA Line Value in PG25 cannot exceed CBP's entry value – this business rule is validated by CBP; In case of multiple PG25 records to enter different lot numbers, the line value must be entered in only the first PG25 record; Clarified that Quantity in PG26 is always entered with 2 implied decimals; Clarified the description of the Packaging Qualifier for PG26; Introduced the use of the new PG Message Record PG60 and the use of PG07, PG19, PG20 and PG21 records is affected by PG60; Deleted the Note for PG24 to include the effect of PG60 and removed PG24:NAM construct; Synchronized the Intended Use Codes to the Appendix R -DRAFT 2015-12-01H.docx; PG30:Inspection or Arrival Location Code is set to '2' and the valid port code is entered in the PG30:Arrival Location; The Entity role code UC is interpreted to be synonymous to DP for Prior Notice – Combined Entry; for all other chapters, text for this interpretation is removed; The disclaimer code 'B' is removed; PG06:Country Code should match the Country Code in PG19-PG20 record set depending on PG06:Source Type Code and PG19:Entity Role Code; Entity role code 'LG' is removed from the applicable roles list for all non-PN chapters; LG is used only for PN purposes; AoC codes CCN, UFC and HTS are removed; PG01: record layout changed to reflect CBP inclusion of 'Correction Indicator' in position 79; Clarified the title of PG30 to include Port of Arrival / Entry; adjusted the field names in PG30 accordingly; added the port of Entry data requirements to PG30 across all chapters; All the other applicable entity roles for PG19, except PK, are removed from all chapters; Removed all references to Fax Number for a POC in PG21; **Biologics:** Removed the requirement for lot# in PG25; Removed PG05 / PG07 notes not needed anymore; Added clarification to Note1 for PG07 regarding HCT products; Clarified that FEI is preferred over DUNS in PG19 similar to CDRH rules; Replaced the IUC codes table for PG01 based on CBER feedback dated 2/23/2016; Replaced the AoC codes table for PG23 based on CBER feedback dated 2/18/2016;	Multiple pages

Date	Version No.	Description	Page Number
		Replaced the Import Scenario table for PG23 based on CBER feedback dated 2/23/2016; PG04 is optional; **Tobacco:** Added 'PCS' as a valid Unit of Measure base unit; made PGA Unit Value optional; All AoC Codes are optional in PG23 based on CTP feedback; Correction: FEI is not required in PG19; **Medical Devices:** Added BD+6N to AoC code PM# in PG23 based on CBER feedback; Source Type Code of 30 is for components and 39 for finished devices in PG06; Brand Name is conditional for PG07 and added the condition in a note; **Food (non-PN):** Clarified AoC code FCE can be from 5 to 10 digits; Clarified PNC# should be a 12 digits number; Clarified the use of Source Type Code in PG06; Clarified the format of AoC Code SID in PG23 as CCYYMMDDnnn for 11 digits; AoC Cods FCE and SID are required for LACF and AF; additionally, either the AoC code VOL or PG28 is required; this clarifies the use of AoC Codes SID, FCE and VOL to be in line with the most recent NPRM; **Prior Notice (PN):** Program Code CCW is removed from the combined entry chapter; PG28 is edited to allow for the SCAC to be submitted; PE10: Ref.Qual.Code changed from BIL to BOL based on recent CBP changes; Clarified the use of Source Type Code in PG06; Clarified the rule for PG13:LPCO; Clarified the choice of Grower or Consolidator in PG19; Added the AoC code LFR for Location of Foods (Holding Facility); Govt. Agency Processing Code 'CCW' is not applicable to the Combined Entry chapter; Entity Role Code 'LG' was included in both the PN Stand-Alone chapter and the Combined Entry chapter but with inconsistent condition; corrected this inconsistency to use the same description / condition in both these chapters; AoC code VFT is required when it exists. 'Does Not Exist' can be entered if Trip # is not known; AoC Code FME should be followed by a 1-letter code based on the newly named Appendix B; AoC Code RNO in PG23 can be repeated for multiple rail car numbers; if rail car number is not known, then 'Does Not Exist' can be entered; PG27 record is repeatable with 3 container numbers per record;	

Date	Version No.	Description	Page Number
		Animal Drugs & Devices: PG04 is not required for VME/ADE; it can be entered for VME/ADR; Clarified the description to include multiple GD records in PG19 for multiple API producers; GD is optional; AoC codes are conditional if the Government Agency Program Code = VME and Government Agency Processing Code = ADR; there are currently no AoC codes for ADE; AoC Code REG is conditional; AoC Code NDC is optional; AoC Code DLS is optional; AoC Code VFL is optional; AoC Code VFD (=Veterinary Feed Directive) is optional; Added UoM CAP (Capsules) and CTR (Cartridge) to PG26/PG29 and Appendix D; **Radiation Emitting Products:** Clarified the rules for entering the AoC codes ACC and ANC in PG23; Brand Name is conditional for PG07 and added the condition in a note; Clarified AoC Codes 'ACC' and 'ANC': added the syntax and format; required if RB1 is entered; Clarified AoC Code RB1: required if either ACC or ANC is entered; no qualifier Added an optional AoC Code 'MDL' where the filer can enter the model number of the product; Added an optional AoC Code 'CCM' for Certified Component Manufacturer; **Drugs:** Removed Appendix B and Appendix C and re-named the rest of the appendices; this affects the references to appendices in other chapters as well; Clarified that PG04 is not required for DRU/PHN but is optional for other processing codes within DRU; Clarified the description to include multiple GD records in PG19 for multiple API producers; GD is optional; Expanded the definition of the processing code 'PHN' to include Pharmaceutical Necessities, Inactive Pharmaceutical Ingredients and Excipients; Clarified the use of PG04 for APIs and deleted the 2nd example for API; clarified the rules in Note2 and Note3 for PG04; Added UoM CAP (Capsules) and CTR (Cartridge) to PG26/PG29 and Appendix D; Restated the rule when PG23 will not be required; added notes to the AoC code 'DLS' in the case of a Private Label Distributor (PLD); Added syntax to the AoC code LST in PG23; Included the missing Intended Use Codes in the AoC code rules due to changes in CBP's Schedule R;	

Date	Version No.	Description	Page Number
		Added a new editing rule for the PIC in the FDA product code based on government agency processing code (in PG01) and Intended Use Code (in PG01); Added capsules (CAP) and cartridges(CTR) as unit of measurement values in PG26/PG29; **Cosmetics:** Clarified the text for Government Agency Processing Code in PG01; Only 39 is allowed as a valid source type code in PG06; Country of Source is not applicable to PG06;	
11/30/2016	2.5	**For all commodities:** Clarified the mapping among the Government Agency Program Codes, Government Agency Processing Codes and the corresponding Industry Codes in the Commodity Type list; PG06: Relaxed the requirement for the Country Code for the Country of Production be the same reported in PG19:PG20:MF; PG21: Clarified the mandatory and optional requirement for this record type; PG23: Affirmation of Compliance Qualifier changed from 30AN to 30X; PG25: this record is optional since the line value is not required; PG25: Removed the Note 1 pertaining to a CBP validation of values for all the FDA lines within an entry; PG26: this record is optional, except for Prior Notice and Radiation Emitting Products that are subject to 2877 performance standards; PG29: This record type is removed ; PG30: Port of Arrival/Entry is now correctly named as Anticipated Port of Arrival/Entry; PG30: For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required; PG55: Moved the notice “Not Supported by the FDA at this time” to the front of the page for better readability PG00: Clarified the use of this record type; **Biologics:** Edited this chapter based on CBER feedback in FDA Supplemental Guide 2.5 CBER Revisions & Comments - 31 OCT 2016.docx and FDA Supplemental Guide Release 2.5 draft CBER comments 111816 with tracking.docx; PG02: Added the requirement that the Industry Code in the FDA product code should be 57; PG23: Edited Import Scenarios #10 and #12 to reflect the most recent comments from CBER; **Cosmetics:** PG02: Added the requirement that the Industry Code in the FDA product code should be 50 or 53;	Multiple pages

Date	Version No.	Description	Page Number
		Food: PG02: Clarified the PN validation criteria to include Industry Code = 52; PG02:added a check for industry code (52) when the program/processing codes are FOO/CCW; PG02: re-stated the PN validation logic based on input from DFDT and ORA; PG21: added back the optional entry of filer/broker's Fax# using an optional PG21 record; PG19: added emphasis (highlighted) that **only one** of MF/DFI/FDC is allowed for Prior Notice; PG19: The entity role code FD1 is not required for PN-only chapter; Renamed the 3rd Food chapter to correctly state the intent of this chapter: Non-PN Food Commodity OR PN Requirements Previously Met; PG21: The entity role code FD1 is not required for PN-only and PN-Combined-Entry chapters; it is required for FOO-CCW entries; PG19-PG20-PG21: Added the role code FSV (Foreign Supplier Verification Program) for non-PN; PG23: Added new AoC codes FSX and RNE to support the entity role code FSV for non-PN; **Animal Drug and Devices:** PG01: updated the list of Intended Use Codes based on feedback from CVM; PG02: Added the requirement that the Industry Code in the FDA product code should be 68 for VME/ADE; added the requirement that the Industry Code in the FDA product code should be a valid value in 56, 60, 61, 62, 63, 64, 65, 66, 67 or 54 and (subclass code is ('N', 'R') for VME/ADR; PG23: updated the IUC list based on changes to PG01 above; re-wrote the table of mapping between the IUCs and AoCs; PG23: removed the AoC code IFE from the VME chapter; PG26: deleted the UoM table for this chapter; Appendix D has the valid UoM codes; PG27: deleted this record to bring this chapter in sync, with DRU chapter; **Medical Devices:** PG02: Added the requirement that the Industry Codes in the FDA product code should be between 73 and 92; PG19: Clarified the requirement for entering the entity Device Initial Importer (DII); PG23: The AoC code DDM is now conditional for the Intended Use Code 170.000; PG23: The AoC code ERR is allowed; **Radiation Emitting Products:** PG02: Added the requirement that the Industry Codes in the FDA product code should be between 94 and 97;	

Date	Version No.	Description	Page Number
		PG23: The AoC codes ERR and IFE are allowed; **Tobacco:** PG02: Added the requirement that the Industry Code in the FDA product code should be 98; PG07: the brand name is not required if the processing code is INV; PG19: Submitter (TB) is now an allowed entity - it is no longer mandatory; **Drugs:** PG01: The list of Intended Use Codes is adjusted per feedback from CDER; mapped the new IUCs to Form/Type of drugs; PG02: Added the requirement that the Industry Code in the FDA product code should be a valid value in 50, 55, 56, 60, 61, 62, 63, 64, 65, 66 or 54 and (subclass code is ('D', 'E', 'F', 'G', 'I'); PG04: updated the new applicable IUCs to the rules; PG19: adjusted the optional entities per CDER feedback; PG23: updated the IUC list based on changes to PG01 above; re-wrote the table of mapping between the IUCs and AoCs; PG26: replaced the UoM table per feedback from CDER;	
12/9/2016	2.5	**For all commodities:** PG21: Added sentence "If provided, there should be only one PK per line," to introductory text; **For specific commodities:** Deleted 50 and 55 from VME – Animal Drug in the FDA Commodities, Commodity Sub-Types & Corresponding Industry Codes chart; **Appendix D:** Added CTR code with description of Cartridge to the FDA Unit of Measurement Codes list; **Change Log**: **Animal Drugs and Devices** PG02: Deleted duplicate PG02 change log entry; PG02: Added 67 to the list that should have a valid value for Industry Code in the FDA product code; **Change Log: Drugs** Added 50 and 55 to the list that should have a valid value for Industry Code in the FDA product code;/2016	Multiple pages
12/12/2016	2.5	**For all commodities:** PG21: Clarified instructional information;	Multiple pages

Date	Version No.	Description	Page Number
12/28/2016	2.5	**Stand Alone Prior Notice:** PG19: FD1 conditional requirement has been re-added (See 11/30/2016 changelog entry); **Animal Drugs and Devices:** PG07: Modified the Record Identifier table title. Also modified the “Trade Name/Brand Name” data element’s status and description on the Record Identifier table;	Multiple pages

General Introduction

This document is intended as supplementary instructions to the CBP Customs and Trade Automated Interface Requirements (CATAIR), PGA Message Set chapter (also referred to as an implementation guide). The FDA PGA Message Set provides specific instructions for the filing of FDA-regulated commodities.

The PGA Message Set chapter/implementation guide and its related Appendix PGA can be found on CBP.gov at:
http://www.cbp.gov/document/guidance/appendix-pga

The ACE ABI CATAIR – Custom and Trade Automated Interface Requirements:
http://www.cbp.gov/document/guidance/pga-message-set

Appendix V Government Agency Codes:
http://www.cbp.gov/document/guidance/appendix-v-government-agency-codes

Appendix R Intended Use Codes for ACE:
http://www.cbp.gov/document/guidance/appendix-r-intended-use-codes-ace

Appendix B Valid Codes:
http://www.cbp.gov/document/guidance/appendix-b-valid-codes

Appendix C:
http://www.cbp.gov/document/guidance/appendix-c-tariff-abbreviations

FDA Overview

FDA is responsible for:

- Protecting the public health by assuring that foods (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary and properly labeled; ensuring that human and animal drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective,
- Protecting the public from electronic product radiation,
- Assuring cosmetics and dietary supplements are safe and properly labeled,
- Regulating tobacco products, and
- Advancing the public health by helping to speed product innovations.

Primary responsibility for administering the nation's laws relating to import, export, and the collection of duties is given to the United States Customs and Border Protection (CBP). FDA, however, is responsible for determining whether or not an article offered for importation is in compliance with or in violation of the acts enforced by the FDA. This includes the responsibility of determining whether or not a violative article may be brought into compliance with the appropriate statute and/or regulations, and authorizing reconditioning in order to bring an article into compliance. In order to fulfill their respective responsibilities, CBP and FDA work in close cooperation.

Points of Contact

For technical questions about the content of this document, please email FDA's ACE Help Desk at ACE_Support@fda.hhs.gov.

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Legends

Field Requirements

Abbreviation	Name	Description
M	Mandatory	This data element is required under all circumstances
C	Conditional	This data element is required under certain circumstances as defined by corresponding notes.
O	Optional	This data element is not compulsory under all circumstances

Field Data Types

Abbreviation	Name	Description
A	Alpha	Letters A-Z
N	Numeric	Numbers 0-9
AN	Alphanumeric	Letters A-Z and Numbers 0-9
X	Alphanumeric and Special Characters	Letters A-Z, Numbers 0-9, special characters (*,!,@, etc.)

Required (Mandatory and/or Conditional)Data Elements for all FDA Commodities

Level of Data	Record ID	Data Element	Length/ Class	Position	Field Type
Entry	OI	Record Identifier			
Line	PG01	PGA Line Number	3N	5-7	incremental
Line	PG01	Government Agency Code	3AN	8-10	code
Line	PG01	Government Agency Program Code*	3X	11-13	code
Line	PG01	Government Agency Processing Code*	3AN	14-16	code
Line	PG02	Item Type	1A	5	code
Line	PG02	Product Code Qualifier	4AN	6-9	code
Line	PG02	Product Code Number	19X	10-28	text
Line	PG06	Source Type Code	3AN	5-7	code
Line	PG06	Country Code	2X	8-9	code
Line	PG10	Product Description	57X	24-80	text
Line	PG19	Entity Role Code	3AN	5-7	code
Line	PG19	Entity Name	32X	26-57	text
Line	PG19	Entity Address 1	23X	58-80	text
Line	PG20	Entity City	21X	42-62	text
Line	PG20	Entity Country	2A	66-67	code
Line	PG21	Individual Name	23X	8-30	text
Line	PG21	Telephone Number of the Individual	15X	31-45	text
Line	PG21	Email Address for the Individual	35X	46-80	text
Line	PG30	Inspection/ Laboratory Testing Status	1A	5	code
Line	PG30	Anticipated Arrival date	8N	6-13	date
Line	PG30	Anticipated Arrival time	4N	14-17	time

*Not Required for a Disclaimed entry

FDA Commodities, Commodity Sub-Types & Corresponding Industry Codes

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
BIO - Biologic	ALG - Allergens	57
	BLO - Blood & Blood Products	
	CGT - Cell and Gene Therapy	
	HCT - Human Cells & Tissue	
	VAC - Vaccines	
	XEN - Xenotransplants	
	BDP - Blood Derivatives	
	BBA - Blood Bag with anti-coagulant	
	BLD - Licensed Devices	
	PVE - Plasma Volume Expanders	
COS - Cosmetic	N/A	50 or 53
DRU – Drug*	PRE - Prescription	50, 54, 55, 56, 60, 61, 62, 63, 64, 65, or 66
	OTC - Over the Counter	
	RND - Research & Development	
	INV - Investigational	
	PHN - Pharmaceutical Necessities	55, various codes could apply
VME - Animal Drug or Device*	ADR - Animal Drug	54, 56, 60, 61, 62, 63, 64, 65, 66 or 67
	ADE - Animal Device	68
FOO – Food*	NSF - Natural State Food	01-46, 48, 49, 50, 52, 54, 69, 70, 71 or 72
	PRO - Processed Food	
	FEE - Animal Feed	
	DSU - Dietary Supplement	
	ADD - Additives and Colors	
	CCW - Ceramicware or Food Contact Substance	52
DEV - Medical Device	NED - Non-Radiation Emitting Device	73-92
	RED - Radiation-Emitting Device	
RAD - Radiation-Emitting Products	REP - Non-Medical Radiation-Emitting Product	94-97
TOB - Tobacco	CSU - Consumer Use	98
	FFM - For further manufacturing	
	INV - Investigational	

* Subject to additional rules based on FDA Program/Processing/Product codes. See PG02 in individual chapters.

Biologics Commodity Data Elements and Values

Biologics commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Biologics	BIO	Allergens	ALG
FDA	Biologics	BIO	Vaccines	VAC
FDA	Biologics	BIO	Human Cells & Tissue	HCT
FDA	Biologics	BIO	Xenotransplant	XEN
FDA	Biologics	BIO	Cell & Gene Therapy	CGT
FDA	Biologics	BIO	Blood and Blood Products	BLO
FDA	Biologics	BIO	Licensed Devices	BLD
FDA	Biologics	BIO	Blood Derivatives	BDP
FDA	Biologics	BIO	Blood Bag with Anti-coagulant	BBA
FDA	Biologics	BIO	Plasma Volume Expanders	PVE

Table 1 – Biologics commodity hierarchy

Note:
The government agency processing code BRD, the corresponding Intended Use Code, and Affirmation of Compliance Codes (PM# and IDE) have been removed from the Biologics Commodity Data Elements and Values section. These devices will be handled using the Medical Device Commodity Data Elements and Values in the ACE/ITDS environment.

The following are the potential PGA records associated with submitting Biologics data:

PG Record	Description
OI	The commercial description of the shipment is provided.
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	The item type and Product Code detail are provided.
PG04	Product Constituent Active Ingredient
PG05	Scientific Genus Names
PG06	Product Source information is provided
PG07	Trade/Brand Name
PG10	Description of items in the lot number

PG Record	Description
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1 are provided.
PG20	Additional address data on the entity in PG19 is provided
PG21	The entity (manufacturer, consignee, shipper, etc.) of Record's individual point of contact, phone number and email is given.
PG23	FDA affirmation of Compliance criteria is provided
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Additional data on Container number
PG30	Inspection location, date and time
PG55	Additional roles performed by entity or individual
PG60	Additional Information
PG00	Data Substitution

Biologics Example

Biologic Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.5 Example PG Message Sets.xlsx** Tab: ***Biologics***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message Set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must be “OI”	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, BLOOD DERIVATIVES	

Record Identifier PG01 (Record Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (*Record Identifier*)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"BIO"	1, 2, 3
Government Agency Processing Code	3AN	14-16	C	Allowed values for Biologics sub-types: ALG, VAC, HCT, XEN, CGT, BLO, BLD, BDP, BBA and PVE.	1, 2, 3
Intended Use Code	16X	42-57	C	Refer to the table below for valid values	1,4, 5
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	"A" (= product is not regulated by this agency) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	3

Note 1
For entries of human hemotopoietic stem cell and reproductive tissue (BIO/HCT/ Product Code 57K and 57M), use Intended Use Code 082.000. 082.000 Intended Use Code is for the immediate use by authorized medical officials in the medical treatment of humans. However, several other Intended Use Codes could also be applicable (see PG23 table for Scenario based use of the AofC codes). Submitting "UNK" as the Intended Use Code will subject the entry to manual review, which will cause delays

Note 2
See Table 1 above for the commodity hierarchy for Biologic commodities

Note 3
If the product is to be disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code and Government Agency Processing Code are mandatory.

Note 4
Unless the line is disclaimed, Intended Use Code is mandatory.

Note 5 Intended Use Codes available for Government Agency Program Code BIO:

CBER Regulated Products Import Scenario	**Intended Use Code**	**CBP Intended Use Name**

CBER Regulated Products Import Scenario	Intended Use Code	CBP Intended Use Name
CBER-regulated Final Product (includes licensed biological products, drugs or devices) ; ready for use	**080.000**	For Human Medical Use as a Non-Food Product under Controlled Distribution
Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient	**082.000**	For Immediate use by authorized medical officials in the medical treatment of humans
CBER-Import for Export (IFE) under the import for export provisions 801(d) (3), & 801(d) (4) of the FD&C Act.	**970.000**	For Immediate Re-Exportation
CBER Product Sample for testing or lot release	**180.016**	For processing samples submitted to CBER for lot release testing.
Bulk Drug Substance or CBER product for processing into a pharmaceutical product.	**150.007**	For commercial processing as a Non Food product; for processing into a pharmaceutical product.
CBER product For further manufacture of a licensed biological product under a short supply agreement (21 CFR 601.22)*	**155.000**	For Commercial Assembly as a Non-Food Product
Importation for Personal Use	**100.000**	For private non-commercial use under the FDA personal importation policy (PIP)
Standard import of a biological drug or device for non-commercial distribution in government and non-government organization support program	**140.000**	For Charitable Organization Use as Non-Food Product. Eg:For improving living conditions during a natural disaster.
Biological or chemical for research and development into a pharmaceutical product – Investigational New Drugs (IND); clinical trials or other human/animal	**180.009**	Biological or chemical for research and development into a pharmaceutical product
Import of biologic for non-clinical research use only, bench testing, etc.. These entries could be disclaimed if the HTS code allows it.	**180.000**	For Research and Development as a Non-Food Product
Import of biological drug or device for trade show	**110.000**	For Public Exhibition or Display as a Non-Food Product
For reconditioning or repair of a Non-Food. Product	**170.000**	For repair of a Non-Food Product
Importation of a drug (including a biological product) or device for compassionate use/emergency use	**940.000**	Import of a Compassionate Use/Emergency Use Device
US Goods Returned	**920.000**	For return to the US

Note: The government agency processing code BRD, the corresponding Intended Use Code, and Affirmation of Compliance Codes (PM# and IDE) have been removed from the Biologics Commodity Data Elements and Values section. These devices will be handled using the Medical Device Commodity Data Elements and Values in the ACE/ITDS environment.

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to the product. Enter P for product. No other values are allowed. Only one 'P' record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	"FDP" (FDA Product)	
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Product Code Qualifiers and their descriptions can be found in CBP's Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For FDA, this is currently always 'FDP' for all FDA products.

Only one FDA Product Code Number per line is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

<u>*** Edit to limit Industry Codes, dependent upon the Government Agency Program Code ***</u>

IF Government Agency Program Code = 'BIO'
THEN PRODUCT.CODE.INDUSTRY.CODE MUST = 57

Record Identifier PG04 (Product Constituent Element)

This is an optional PGA input record that provides data pertaining to Constituent Active Ingredient Qualifier, Name of the Constituent Element, Quantity of Constituent Element, Unit of Measure, and Percent of Constituent Element for the product identified by Product Code Number in PG02. This record can be repeated.

See Appendix C for an example of how PG04 can be used at the Product-level for multiple Constituent Elements.

Record Identifier PG04 (Product Constituent Element)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"04"	
Constituent Active Ingredient Qualifier	1A	5	O	Active ingredient = "*Y*" if yes, blank if no.	1
Name of the Constituent Element	51X	6-56	O		1
Quantity of Constituent Element	12N	57-68	O	2 decimal places are implied	1
Unit of Measure (Constituent Element)	5AN	69-73	O		1
Percent of Constituent Element	7N	74-80	O	4 decimal places are implied. 18.2% is entered as 0182000.	1, 2

Note 1
Some of the Biologics products may not have a defined active ingredient. Even when an active ingredient is known, it may be in a descriptive form. For example, the multiple active ingredients in the MMR Vaccine are expressed in detail in the Prescribing information.

Note 2
Examples of Percentages:

1000000	=	100%
0990000	=	99%
0090000	=	9%
0009000	=	.9%
0000900	=	.09%
0000090	=	.009%
0000009	=	.0009%

Record Identifier PG05 (Scientific Genus Names)

This is an optional PGA input record that provides data pertaining to Scientific Genus Names, Scientific Species, Scientific Sub Species Name, Scientific Species Code, for the product identified by Product Code Number in PG02.

The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time.

Record Identifier PG05 (Scientific Genus Names)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“05”	
Scientific Genus Name	22X	5-26	O	Scientific Genus Name of the merchandise being entered.	
Scientific Species Name	22X	27-48	O	Scientific Species Name of the merchandise being entered.	
Scientific Sub Species Name	18X	49-66	O	Scientific Sub Species Name of the merchandise being entered.	

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) - other than the CBP Country of Origin - for the product identified by Product Code Number in PG02.

The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	Mandatory valid value is 39 (Country of Production) or 30 (Country of Source). 294 (Country of Refusal) is MANDATORY if previously refused. There will be at least one PG06 with source type code of 30 or 39. If previously refused, then trade would also provide another PG06 with source type code 294.	1
Country Code	2X	8-9	M	Country of production or source is required for Biologics.	2

Note 1

Source Type Codes and their descriptions can be found in CBP's Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from CBP's Appendix B (ISO Country and Currency Codes) in the ACE ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

For Biologics, this is a conditional PGA input record that provides data pertaining to Trade or Brand Name of the product identified by Product Code Number in PG02.

The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name	35X	5-39	C	If Government Agency Program Code = 'BIO' and if a product is licensed under ALG, BDP, BLD, BLO, CGT, VAC, or XEN government agency processing codes then Trade Name/Brand Name or Proper Name is mandatory (Note 1 *) If Government Agency Program Code = 'BIO' and if the product is coming under BBA or PVE government agency processing codes then Trade Name/.Brand Name or Proper Name is Mandatory (Note 1 **) If Government Agency Program Code = 'BIO' and if the product is coming under HCT government agency processing code then Trade Name/Brand Name/Proper Name is Optional. (Note 1 ***) The make of the product (or component) by manufacturer or distributor from the label or invoice. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code 'TBN'.	1

<u>Note 1:</u>

* ALG, BDP, BLD, BLO, CGT, VAC or XEN government agency processing codes apply to CBER regulated licensed biological products. Trade Name/Brand Name is mandatory if it exists. If no Trade Name is available provide the proper name. Per 21CFR600.3 (k), *Proper name is defined* as the name designated in the product license, for use upon each package of the product.

** BBA or PVE government agency processing codes apply to drug products regulated by CBER (NDA and ANDA under 505 of the FD&C Act). Trade Name/Brand Name is mandatory if it exists for the NDA or the ANDA. If no Trade Name is available provide the proper name.

*** HCT government agency processing code applies to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) which do not have a trade name or proper name. Trade Name/Brand Name is Optional. But providing description would aid in facilitating the entry admissibility decision. (PG01 - Government Agency Processing Code =HCT)

Record Identifier PG10 (Product Characteristics)

For Biologics this is a mandatory PGA input record that allows for importer to report the description of the product identified by Product Code Number in PG02 at the line level to capture the information currently collected in multiple OI records.

The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“10”	
Commodity Characteristic Description	57X	24-80	M	Include proper name (if applicable) OR invoice description here - NOT product code description. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Biologics, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role, Entity Name and Entity Address 1. .

Entity Identification Code and Entity number are optional data elements, but they are listed as conditional because if opting to transmit Entity Identification Code then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example: 16 (DUNS #), 47 (FEI#). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code 'ENA'. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code 'AD1'. See validation criteria below.	2

Note 1
Entity Role Codes and their descriptions can be found in CBP's Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Biologics Message Sets is below. One of each of these is mandatory for EACH LINE:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party

§ Same Role Code cannot be entered more than once.

List of Entity Role codes optional to FDA Biologics Message Sets:

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Note 2

Entity Identification Code and Entity Number are optional. However, if opting to enter an Entity Identification Code, Entity Number must also be provided, and vice versa. List of Entity Identification codes applicable to FDA Biologics Message Sets is below:

Data Element	***Code***	***Description***	***Length/ Class***
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 4 to 10 digits	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA/CBER highly recommends the transmission of an FEI numbers for identifying the Entity; IF FEI is not available THEN DUNS number may be provided. For CBER, the vast majority of registration numbers are FEIs.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length = from 4 to 10 and Type = N
ELSE IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used to enter additional address information for the entity.

Record Identifier PG20 (Entity Address)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code 'AD2'.	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	
Entity City	21X	42-62	M	City of the entity. If Entity City requires additional space, continue in a PG60 record with Qualifier Code 'ECI'.	
Entity State/Province	3AN	63-65	C	State/Province of the entity. See CBP's Appendix B in the ACE ABI CATAIR for valid codes.	2
Entity Country	2A	66-67	M	ISO Country Code. See CBP's Appendix B in the ACE ABI CATAIR for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	M	Space fill	

Note 1: If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes 'AD3', 'AD4' and 'AD5' immediately under the PG20 record for the same Entity.

Note 2: Required if US or Canada based entities.

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides point of contact information.

For each FDA entry line, at least one PG21 is required with the individual qualifier “FD1” (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier “PK” which should be the point of contact for the filer/broker. “PK” may be sent in one of the following ways:

- under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer) *FDA preferred method
- or as a secondary PG21 to FD1 using individual qualifier “PK” (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), or
- under any other required PG19 entity as long as “PK” is the individual qualifier in PG21.

If provided, there should be only one PK per entry line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“21”	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only FD1 and PK are allowed.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code ‘INA’.	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address needs more space, continue in a PG60 record with Qualifier Code ‘EMA’.	

Record Identifier PG23 (Affirmation of Compliance)

For Biologics, this is a conditional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. See CBP's Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the FDA. This could include a number or a country code, etc. Also, see CBP's Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) for valid codes related to certain specific Affirmation of Compliance codes.	
Filler	1X	80	C	Space fill	

Note 1
Below is the list of Affirmation of Compliance codes for FDA-Biologics Message Sets, followed by the scenarios when the AofCs are provided: N= Numeric Digits; X = Alphanumeric including special characters

AoC Code	***Description***	***Syntax***
DA	Biologics New Drug Application Number or Abbreviated New Drug Application Number (NDA or ANDA)	BA+4-6N or BN + 5-6 N or 6N
HRN	Biologics Human Cells, Tissues/ Cellular and Tissue-Based Product Establishment Registration Number (HCT/P Registration Numbers)	10N
IND	Biologics Investigation New Drug Application Number	4-6N
HCT	Human Cells & Tissue	Indicator only
BLN	Biologics License Number	4N
STN	Biologics Submission Tracking Number	6N
CPT	Component Identifier	Indicator only
IFE	Import For Export	indicator only
REG	Drug Registration Number	4-10N
DLS	Drug Listing Number	10N

Note 2

For entries of human hemotopoietic stem cell and reproductive tissue (BIO/HCT/ Product Code 57K and 57M), use Intended Use Code 082.000. 082.000 Intended Use Code is for the immediate use by authorized medical officials in the medical treatment of humans. However, several other Intended Use Codes could also be applicable (see table below for Scenario based use of the AofC codes). Submitting "UNK" as the Intended Use Code will subject the entry to manual review, which will cause delays.

Scenario based use of the above AoC codes

#	Government Agency Processing codes for BIO	CBER Regulated Products Import Scenario	Intended Use Codes	CBP Intended Use Name	Mandatory	Optional
1	ALG, BBA, BDP, CGT, PVE, VAC, or XEN	Biological or chemical for research and development into a pharmaceutical product – Investigational New Drugs (IND); clinical trials or other human/animal use	180.009	For Research and Development of a pharmaceutical product	IND	REG
2	ALG, BDP, BLD, BLO, CGT, VAC, or XEN	CBER-regulated Final product; ready for use. Importation of a licensed biological product. The Biologics License number (BLN) is the U.S. License Number. The Submission Tracking Number (STN) is associated with the manufacturer and a specific product and the first six digits represent the original submission tracking number.	080.000	For Human Medical Use as a Non-Food Product under Controlled Distribution	BLN or STN or both	REG, DLS
3	BBA, PVE	CBER-regulated Final product; ready for use. Importation of drug regulated by CBER.	080.000	For Human Medical Use as a Non-Food Product under Controlled Distribution	DA, REG, (DA includes NDA and ANDAs only)	DLS
7	HCT	Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient. The HCT affirmation should be used to indicate the HCT/Ps being importer or offered for import are in compliance with all applicable requirements of 21 CFR 1271.	082.000	For Immediate use by authorized medical officials in the medical treatment of humans	HCT (No Qualifier Needed for HCT)	
8	HCT	Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient. The HRN Affirmation should be used	082.000	For Immediate use by authorized medical officials in the medical treatment of	HRN	HCT

#	Government Agency Processing codes for BIO	CBER Regulated Products Import Scenario	Intended Use Codes	CBP Intended Use Name	Mandatory	Optional
		for Importation of human cells, tissues and cellular and tissue-based product where the establishment is registered with the FDA.		humans		
9	ALG, BDP, BLD, BLO, CGT, VAC, or XEN	CBER Product sample for testing or lot release	180.016	For processing samples submitted to CBER for lot release testing.	BLN or STN or both	REG, DLS
10	ALG, BLO, BLD, BDP, VAC, XEN, or CGT.	CBER product For further manufacture of a licensed biological product under a short supply agreement (21 CFR 601.22)*	155.000	For processing into a pharmaceutical product	BLN or STN or both	REG, DLS
11	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	Importation for personal use	100.000	For private non-commercial use under the FDA Personal importation policy (PIP)		
12a	ALG, BDP, BLD, BLO, CGT, VAC, or XEN	Bulk biological drug substance for processing into a pharmaceutical product	150.007	For commercial processing as a non- food product; for processing into a pharmaceutical product.	BLN or STN or both	IND, REG, DLS
12b	BBA or PVE	Bulk drug substance for processing into a pharmaceutical product	150.007	For commercial processing as a non- food product; for processing into a pharmaceutical product.	DA	IND, REG, DLS
13	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	Standard import of a biological drug or device for non-commercial distribution in government and non-government support program.	140.000*	For improving living conditions during a natural disaster.		BLN, STN, DA, IND
14	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	Import of a biological drug or device for trade show	110.000*	For public exhibition or display as a non-food product.		BLN, STN, DA, IND

#	Government Agency Processing codes for BIO	CBER Regulated Products Import Scenario	Intended Use Codes	CBP Intended Use Name	Mandatory	Optional
15	ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE, VAC, or XEN	For reconditioning or repair of a non-food product	170.000*	For repair of a non-food product.		BLN, STN, DA, IND, HCT, HRN,
16	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	Importation of non-compliant articles (including blood, blood components, Source plasma and source leukocytes) under the import for export provisions 801(d) (3), & 801(d) (4) of the FD&C Act.	970.000*	Import for Export	IFE (No qualifier required)	
17.	BLO, ALG, BBA, BDP, BLD, CGT, HCT, PVE, VAC, or XEN	Import of a biologic for non-clinical research use only, bench testing, etc. These entries could be disclaimed if the HTS code allows it.	180.000	For Research and Development as a Non-food product.		
18	ALG, BLO, CGT, HCT, VAC, XEN, BDP, BLD, BBA, PVE	Importation of a drug (including a biological product) or device for compassionate use/emergency use	940.000*	Compassionate Use/Emergency Device		BLN, STN, DA, IND, HCT, HRN
19	ALG, BLO, CGT, HCT, BAC, XEN, BDP, BLD, BBA, PVE	Import of US Goods Returned	920.000	For return to the United States (US Goods Returned).		

*Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

NOTE: The government agency processing code BRD, the corresponding Intended Use Code, and Affirmation of Compliance Codes (PM# and IDE) have been removed from the Biologics Commodity Data Elements and Values section. These devices will be handled using the Medical Device Commodity Data Elements and Values in the ACE/ITDS environment.

The list of AoC codes **optional** to FDA Biologics Message Sets is below:

Data Element	*Code*	*Description*	*Syntax*	*Business Rules*
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks. Remark Type Code should be GEN.

If GEN, the PG24 is applicable to the preceding PG02. Only one PG24:GEN is allowed per PG02 (this is to avoid multiple PG24:GEN records without a guaranteed sequencing as intended by the filer).

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”24”	
Remarks Type Code	3X	5-7	O	FDA uses only GEN as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Record Identifier PG25 (Product Condition)

For Biologics, this is an optional PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production, Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers. If transmitting a line value, transmitted, the line value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen R=Refrigerated/Chilled, D=Dry Ice H=Fresh, U=Uncontrolled P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A = product B = container C = conveyance	
Lot Number Qualifier	1AN	15	O	Code of the entity that assigned the Lot number. For Biologics the only valid value is: 1 = Manufacturer Should not be entered if more than one PG25 record is entered	
Lot Number	25X	16-40	O	The lot number that the manufacturer/ producer/grower assigned to the product.	
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays while the missing information is obtained. If entered: The value associated with the PGA line number is in whole dollars. Should be entered only in the first PG25 record in	

				the case of multiple PG25 records. If entered, must be right-justified with preceding zeros and be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

Record Identifier PG26 (Product Packaging)

For Biologics, this is an optional PGA Record that provides data pertaining to Packaging Qualifier, Quantity and Unit of Measure. If included, please adhere to the following rules. This record can be repeated up to six times per unique package size. The first record is used to describe the largest container (outermost container) and the number of containers. The second record is used to describe the contents of the next smallest container. If needed, records 2-6 are used in a similar manner (largest to smallest container). The last quantity record used must describe the actual amount of the product in the smallest container and be a code from the table of base units listed below.

When reporting a different package size of the same product, repeat this record using the method described above.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present. The same unit of measure cannot be used multiple times on the same PGA line. Although product packaging is an optional data element, the record is listed as conditional because if opting to transmit the PG26 data, all positions must be sent (Control Identifier, Record Type, Packaging Qualifier, Quantity, and Unit of Measure).

Record Identifier PG26 (Packaging Data)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	C	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays while the missing information is obtained. If entered, this is the total quantity for the packaging level. Must be greater than zero. Two decimal places are implied. The base quantity must always be the last quantity transmitted. Entering Quantity shall require entering Packaging Qualifier and the Unit of Measure.	2,4
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3,4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2

There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as “fill” and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Biologics Message Sets:

FDA Units of Measure for the Packaging Containers and Base Unit (Last Quantity Transmitted) that apply to Biologics are listed below:

Valid FDA/CBER - Units of Measure for Packaging Containers	
Code	**Description**
AE	Aerosol
AM	Ampoule, Nonprotected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel
BC	Bottle crate, Bottle rack
BG	Bag
BO	Bottle, Non-Protected, Cyl
BQ	Bottle, Protected, Cylindrical
BS	Bottle, Nonprotected, Bulbous
BV	Bottle, Protected Bulbous
BX	Box
CA	Can, Rectangular
CI	Canister
CON	Container
CS	Case
CT	Carton
CX	Can, Cylindrical

Valid FDA/CBER - Units of Measure for Packaging Containers	
Code	**Description**
CY	Cylinder
DR	Drum
EN	Envelope
FD	Framed Crate
GB	Gas Bottle
MB	Bag, Multi-ply
PAL	Pallet
PC	Parcel
PK	Package
SY	Syringe
VI	Vial
TU	Tube
VP	Vacuum Packed
VL	Bulk Liquid

Note: Last unit of measure transmitted must be a Base Unit and only one base unit is allowed:

Valid FDA/CBER - Units of Measure for the Base Unit (Last Quantity Transmitted)		
Code	**Description**	**Measure Type**
AU	Allergy Units (ml or tablet)	Dosage
BAU	Bioequivalent Allergy Units (ml or tablet)	Dosage
CAP	Capsule	Dosage
CG	Centigrams	Weight
FOZ	Ounces, fluid	Volume
G	Grams	Weight

Valid FDA/CBER - Units of Measure for the Base Unit (Last Quantity Transmitted)		
Code	**Description**	**Measure Type**
GAL	Gallons (US)	Volume
KG	Kilograms	Weight
L	Liters	Volume
LB	Pounds (avdp)	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
MCG	Micrograms	Weight
NO	Number	Count
OZ	Ounces, weight (avdp)	Weight
PCS	Pieces	Count
PNU	Protein Nitrogen Units	Dosage
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
TAB	Tablets	Dosage

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pairs may describe the largest container and the last pair must describe the amount of product in the smallest container.
For example: Blood Derivatives: 25 boxes, 8 bottles/box, 1pint each bottle:

Units 1-Quantity= 25
Units 1-Measure =BX
Units 2-Quantity=8
Units 2-Measure=BO
Units 3-Quantity=1
Units 3-Measure=PTL (Note: last unit of measure transmitted must be a base unit).

Record Identifier PG27 (Container Information)

This is an optional PGA input record that provides data pertaining to the shipping Container Number. The Number of the shipping container is included in the Bill of Lading. Hence this record is not needed. This record may be repeated.

Record Identifier PG27 (Container Information)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“27”	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill of Lading.	
Container Number (Equipment ID)	20AN	28-47	O	The number of the shipping container as entered in the Bill of Lading.	
Container Number (Equipment ID)	20AN	51-70	O	The number of the shipping container as entered in the Bill of Lading.	
Filler	7X	74-80	O	Space fill	

Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival/Entry Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is Mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Port of Arrival / Entry Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Inspection/ Laboratory Testing Status	1A	5	M	A = Anticipated arrival information. If entry type = 21, then repeat PG30 and enter F = Foreign Trade Zone.	1
Anticipated Arrival/ Entry date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	1
Anticipated Arrival/ Entry time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	1
Anticipated Arrival / Entry Location Code	4AN	18-21	O	Only a value of '2' (= Census Schedule D representing the CBP port codes) OR 4 (=FIRMS Code) is allowed.	
Anticipated Port of Arrival / Entry	50X	22-71	O	For valid port codes, refer to note 1.	2
Filler	8X	72-80	M	Space fill	

Note 1:

For Non-PN shipments, A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“55”	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Record Identifier PG60 (Additional Information)

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”60”	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	72X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Note 1

Valid Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	**Description**
ENA	Entity Name for PG19
AD1	Entity address Line 1 for PG19
AD2	Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Entity City for PG20
INA	Individual Name for PG21
EMA	Email Address for PG21
TBN	Trade/Brand Name for PG07

PG60 record should follow immediately after its parent. For example, a PG60:ENA record should follow PG19 and a PG60:TBN record should follow PG07.

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping

In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Cosmetics Commodity Data Elements and Values

Cosmetic commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Cosmetics	COS	None	None

Table 2 – Cosmetics commodity hierarchy

The following are the potential PGA records associated with submitting Cosmetics:

PG Record	Description
OI	The commercial description of the shipment is provided.
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	The item type and Product Code detail are provided.
PG06	Source Type(origin) other than the CBP country of origin is provided
PG07	The Trade/Brand Name, Model and Year of Manufacture are provided
PG10	Description of items in the lot number
PG19	The entity (manufacturer, consignee, shipper, etc.) of Record's identification information is provided.
PG20	Additional address data on the entity in PG19 is provided
PG21	The entity (manufacturer, consignee, shipper, etc.) of Record's individual point of contact, phone number and email is given.
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Additional data on Container number
PG30	Inspection location, date and time
PG55	Additional roles performed by entity or individual
PG60	Additional Information
PG00	Data Substitution

Cosmetics Example

Cosmetics Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.5 Example PG Message Sets.xlsx Tab: *Cosmetics***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message Set.

Record Identifier OI (Record Identifier)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“OI”	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, FINE EYELINER	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length /Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"COS"	1, 2
Government Agency Processing Code	16AN	14-16	O	No Processing Code applies for Cosmetics.	1, 2
Intended Use Code	16X	42-57	O		
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	"A" (= product is not regulated by this agency) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	

Note 1
See Table 2 above for the commodity hierarchy for Cosmetic commodity.

Note 2

If the product is to be disclaimed, then these data elements should both be populated with 'FDA'. Otherwise, the Government Agency Program Code is mandatory.

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	1

Note 1

Product Code Qualifiers and their descriptions can be found in CBP's Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For FDA, this is currently always 'FDP' for all FDA products.

Only one FDA Product Code Number per line is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

IF Government Agency Program Code = 'COS'
THEN PRODUCT.CODE.INDUSTRY MUST = 50 or 53

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin..

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	Mandatory valid value is 39 (Country of Production). 294 (Country of Refusal) if previously refused.	1
Country Code	2X	8-9	M	Country of production or source is required for Cosmetics.	2

Note 1

Source Type Codes and their descriptions can be found in CBP's Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from CBP's Appendix B (ISO Country and Currency Codes) in the ACE ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is an optional PGA input record that provides data pertaining to Trade or Brand Name, Model, Manufacture Year, Item Identity Number Qualifier and Item Identity Numbers.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“07”	
Trade Name/Brand Name	35X	5-39	O	Trade or Brand name of the Cosmetic product is entered. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code ‘TBN’.	

Record Identifier PG10 (Product Characteristics)

This is a mandatory PGA input record that allows for reporting codes that provide additional characteristics of a product or component, not reported elsewhere in the PG Message Set. For example, this record can be used to provide the specific type of mascara. .

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“10”	
Commodity Characteristic Description	57X	24-80	M	Free form description (invoice description NOT product code description) of the item. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Cosmetics, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role, entity name and entity address 1.

Entity Identification Code and Entity number are optional data elements, but they are listed as conditional because if opting to transmit Entity Identification Code then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example: MF, DP	1, 3
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example: 16 (DUNS #), 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code 'ENA'. See validation criteria below.	2
Entity Address 1	23X	58-80	M	Must be entered. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code 'AD1'. See validation criteria below.	2

Note 1
Entity Role Codes and their descriptions can be found in CBP's Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Cosmetics Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party

§ Same Role Code cannot be entered more than once.

List of Entity Role codes optional to FDA Cosmetics Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Drug Message Sets is below:

Data Element	***Code***	***Description***	***Length/ Class***
Entity Identification Codes	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity. needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code ‘AD2’.	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	
Entity City	21X	42-62	M	City of the entity. If Entity City requires additional space, continue in a PG60 record with Qualifier Code ‘ECI’.	
Entity State/Province	3AN	63-65	C	State/Province of the entity. See CBP’s Appendix B in the ACES ABI CATAIR for valid codes.	2
Entity Country	2A	66-67	M	ISO Country Code. See CBP’s Appendix B in the ACES ABI CATAIR for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	M	Space fill	

Note 1: If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes ‘AD3’, ‘AD4’ and ‘AD5’ immediately under the PG20 record for the same Entity.
Note 2: Required if US or Canada based entities

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides point of contact information.

For each FDA entry line, at least one PG21 is required with the individual qualifier “FD1” (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier “PK” which should be the point of contact for the filer/broker. “PK” may be sent in one of the following ways:

- under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer) *FDA preferred method
- or as a secondary PG21 to FD1 using individual qualifier “PK” (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), or
- under any other required PG19 entity as long as “PK” is the individual qualifier in PG21.

If provided, there should be only one PK per entry line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“21”	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only FD1 and PK are allowed.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code ‘INA’.	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address needs more space, continue in a PG60 record with Qualifier Code ‘EMA’.	

Record Identifier PG23 (Affirmation of Compliance)

For Cosmetics, this is an optional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	O	A code used to affirm compliance with FDA requirements. . See CBP's Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1
Affirmation of Compliance Qualifier	30X	10-39	O	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see CBP's Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) for valid codes related to certain specific Affirmation of Compliance codes.	1
Filler	1X	80	O	Space fill	

Note 1
The FDA Affirmation of Compliance Codes and their descriptions are listed in the Appendix PGA (Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes) of ACE ABI CATAIR publication. List of Affirmation of Compliance codes CONDITIONALLY MANDATORY (see note 1.1) to FDA-Cosmetics Message Sets:

The list of AoC codes **optional** to FDA Cosmetic Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	COS	Cosmetic Registration Number	7N or 10N	IF Government Agency Program Code = COS THEN COS IS Optional
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow
	IFE	Import For Export	indicator only	

Record Identifier PG24 (Remarks)

For Cosmetics, this is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.
Remark Type Code should be GEN.

If GEN, the PG24 is applicable to the preceding PG02. Only one PG24:GEN is allowed per PG02 (this is to avoid multiple PG24:GEN records without a guaranteed sequencing as intended by the filer

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”24”	
Remarks Type Code	3X	5-7	O	FDA uses only GEN as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Record Identifier PG25 (Product Condition)

For Cosmetics, this is an optional PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers. If opting to transmit line value, the line value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	Optional F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	Optional. If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Optional. Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Optional. Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier	1AN	15	O	Includes Lots and/or Batches Lot Number Qualifier = 1 Should not be entered if more than one PG25 record is entered	
Lot Number	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays while the missing information is obtained. If entered, the value associated with the PGA line number is in whole dollars and must be entered only in the first PG25	

				record in the case of multiple PG25 records. If entered, must be right-justified with preceding zeros and be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

Record Identifier PG26 (Product Packaging)

This is an optional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity, Unit of Measure, Package Identifier, Packaging Method, Package Material, and Packaging Filler. If included, please adhere to the following rules. This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container and must be selected from the list of base units in Appendix D of this guide.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present. The same unit of measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	O	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1
Quantity	12N	6-17	O	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays while the missing information is obtained. If entered, this is the Quantity of the packaging level and Two decimal places are implied. Must be greater than zero. Entering Quantity shall require entering Packaging Qualifier and the Unit of Measure. Example: 000000000400	2
Unit of Measure (Packaging Level)	5X	18-22	O	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. The same unit of measure cannot be used multiple times on the same PGA line.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
For a list of Unit of Measure codes applicable to FDA-Cosmetics Message Sets, refer to Appendix D of this document.

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pairs may describe the largest container and the last pair must describe the amount of product in the smallest container.
For example: **Bubble bath: 25 boxes, 4 bottles/box, 28 fluid oz. each bottle:**

Units 1-Quantity= 25
Units 1-Measure =BX
Units 2-Quantity=4
Units 2-Measure=BO
Units 3-Quantity=28
Units 3-Measure=FOZ (Last Unit of Measure transmitted must be a base unit)

Record Identifier PG27 (Container Information)

This is an optional PGA input record that provides data pertaining to the shipping Container Number. The Number of the shipping container is included in the Bill of Lading. Hence this record is not needed. This record may be repeated.

Record Identifier PG27 (Container Information)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“27”	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill of Lading.	
Container Number (Equipment ID)	20AN	28-47	O	The number of the shipping container as entered in the Bill of Lading.	
Container Number (Equipment ID)	20AN	51-70	O	The number of the shipping container as entered in the Bill of Lading.	
Filler	7X	74-80	O	Space fill	

Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival/Entry Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is Mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Port of Arrival / Entry Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Inspection/ Laboratory Testing Status	1A	5	M	A = Anticipated arrival information. If entry type = 21, then repeat PG30 and enter F = Foreign Trade Zone.	1
Anticipated Arrival/ Entry date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	1
Anticipated Arrival / Entry time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	1
Anticipated Arrival / Entry Location Code	4AN	18-21	O	Only a value of '2' (= Census Schedule D representing the CBP port codes) OR 4 (=FIRMS Code) is allowed.	
Anticipated Port of Arrival / Entry	50X	22-71	O	For valid port codes, refer to note 1.	2
Filler	8X	72-80	M	Space fill	

Note 1:

For Non-PN shipments, A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“55”	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fills.	

Record Identifier PG60 (Additional Information)

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”60”	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	72X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Note 1

Valid Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	**Description**
ENA	Entity Name for PG19
AD1	Entity address Line 1 for PG19
AD2	Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Entity City for PG20
INA	Individual Name for PG21
EMA	Email Address for PG21
TBN	Trade/Brand Name for PG07

PG60 record should follow immediately after its parent. For example, a PG60:ENA record should follow PG19 and a PG60:TBN record should follow PG07.

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping

In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Drug Commodity Data Elements and Values

Drug commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Drugs	DRU	Prescription	PRE
FDA	Drugs	DRU	Over the Counter	OTC
FDA	Drugs	DRU	Pharmaceutical Necessities, Containers, Inactive Pharmaceutical Ingredients and Excipients	PHN
FDA	Drugs	DRU	Research and Development	RND
FDA	Drugs	DRU	Investigational	INV

Table 3 – Drug commodity hierarchy

The following are the potential PGA records associated with submitting Drug:

PG Record	Description
OI	The commercial description of the shipment
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	Product Identifier; the item type and Product Code detail are provided.
PG04	Product Constituent Active Ingredient
PG06	Product Source information is provided
PG07	The Trade/Brand Name
PG10	Product/Component Reporting Code
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1 are provided.
PG20	Additional Entity Identification (Address line 2, Apartment/Suite, City, State, and Zip/Postal Code).
PG21	Additional Entity Role
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided

PG Record	Description
PG26	Packaging qualifier and quantity of the shipment are provided
PG30	Product pertaining to the date, time and location of inspection; previous laboratory testing; inspection location; and anticipated arrival information for FDA
PG55	Additional roles performed by an entity or individual
PG60	Additional Information
PG00	Data Substitution

Drug Example

Drug message set layout sample below:

Please refer to the external file: **FDA SG 2.5 Example PG Message Sets.xlsx Tab: *Drugs***

Drugs Message Set Description

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message Set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“OI”	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, Amoxicillin	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Go**v**ernment Agency Program Code, , Intended Use Code, Intended Use Description, and Disclaimer..

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"DRU"	1, 2, 4
Government Agency Processing Code	3AN	14-16	C	Allowed values: PRE, OTC, INV, PHN, RND	1, 2, 4
Intended Use Code	16X	42-57	C	Refer to the table below for valid values	3, 4
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	"A" (= product is not regulated by this agency) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	2

Note 1

Refer to Table 3 above for commodity type and sub-type for Drugs

<u>Note 2</u>

If the product is to be disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code and Government Agency Processing Code are mandatory.

<u>Note 3</u>

If the product is to be disclaimed, then these data elements are left blank; otherwise the Intended Use Code is required.

Note 4

This is the list of Intended Use Codes available for Government Agency Program Code = "DRU".

Intended Use Code	Intended Use Description
080.012	Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application
100.000	Importation for Personal Use

Intended Use Code	Intended Use Description
130.000	For Consumer Use as a Non- Food Product – Over the Counter (OTC)
150.007	Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding
150.017	Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
155.009	Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
180.009	Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos
180.017	Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal use
180.018	Chemical for research and development of a pharmaceutical product – investigational use in animals
180.026	Finished drug or API intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or, finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements
920.000	US Goods Returned
970.000	Import for Export
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)

Please see the Intended Use codes applicable for Forms and Types:

Prescription (PRE)

Finished Dosage Form:

080.012 Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application

100.000 Importation for Personal Use

155.009 Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)

920.000 US Goods Returned

970.000 Import for Export

980.000 For Other Use: (APIs or Finished Drugs not elsewhere classified)

Active Pharmaceutical Ingredient / Bulk Drug Substance:

150.007 Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product

150.013 Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding

150.017 Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
920.000 US Goods Returned
970.000 Import for Export
980.000 For Other Use: (APIs or Finished Drugs not elsewhere classified)

Over the Counter (OTC)

Finished Dosage Form:

100.000 Importation for Personal Use
130.000 For Consumer Use as a Non-Food Product – Over the Counter (OTC)
155.009 Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
920.000 US Goods Returned
970.000 Import for Export

Active Pharmaceutical Ingredient / Bulk Drug Substance:

150.007 Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product
150.013 Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding
150.017 Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
920.000 US Goods Returned
970.000 Import for Export

Pharmaceutical Necessities, Containers, Inactive Pharmaceutical Ingredients and Excipients (PHN)

No intended use codes for this Commodity Sub-Type

Investigational New Drug (INV)

180.009 Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos
180.026 Finished drug or API intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements
920.000 US Goods Returned

Research and Development (RND)

180.017 Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal use
180.018 Chemical for research and development; investigational use in animals

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P). For Drugs entries, the Product Code Number is provided within this record.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG".	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values are allowed. Only one 'P' record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	"FDP".	
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Only one FDA Product Code Number per line is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

*** Edit to limit Industry Codes, dependent upon the Government Agency Processing Code ***

IF Government Agency Processing Code = PRE, OTC, INV or RND
THEN PRODUCT.CODE.INDUSTRY = 56, 60, 61, 62, 63, 64, 65, 66, or if (Industry_code = '54' and subclass _code is ('D', 'E', 'F', 'G', 'I'))

*** Edit to limit Subclass, dependent upon the Government Agency Processing Code:
C & D are the Subclasses for Rx products;
A & B are the Subclasses for OTC products;
I is the Subclass for Investigational New Drug products ***

IF Government Agency Processing Code = INV
AND PG01 Intended Use Code INCLUDES 180.009, 180.026, or 920.000
THEN PRODUCT.CODE.SUBCLASS = "I"

IF Government Agency Processing Code = PRE
AND PG01 Intended Use Code INCLUDES 080.012, 100.000, 150.007, 150.017, 155.009, 920.000, 970.000, or 980.000

THEN PRODUCT.CODE.SUBCLASS = ‘C’ or ‘D’

IF Government Agency Processing Code = OTC
AND PG01 Intended Use Code INCLUDES 100.000, 130.000, 150.007, 150.017, 155.009, 920.000, 970.000
THEN PRODUCT.CODE.SUBCLASS = ‘A’ or ‘B’

*** Edit to limit Process Indicator Code (PIC) for Active Pharmaceutical Ingredients ***

IF Government Agency Processing Code = PRE or OTC
AND PG01 Intended Use Code = 150.007 or PG01 Intended Use Code = 150.017 Drug to be used as a component in a Medical Device (Active Pharmaceutical Ingredient / Bulk Drug Substance)
THEN PRODUCT.CODE.PIC = ‘S’

IF Government Agency Processing Code = PRE or OTC
AND PG01 Intended Use Code = 150.013 (Active Pharmaceutical Ingredient to be used in pharmacy compounding)
THEN PRODUCT.CODE.PIC = ‘T’

Record Identifier PG04 (Product Constituent Element)

For Drugs, this PGA input record is optional and it provides data pertaining to Constituent Active Ingredient Qualifier, Name of the Constituent Element, Quantity of Constituent Element, Unit of Measure, and Percent of Constituent Element for the product identified by Product Code Number in PG02. This record can be repeated.

Using a Drug example, Appendix C shows how PG04 can be used at the Product-level for multiple Constituent Elements. The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time.

Record Identifier PG04 (Product Constituent Element)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG"	
Record Type	2N	3-4	M	"04"	
Constituent Active Ingredient Qualifier	1A	5	O	If commodity sub-type = PRE, OTC, INV or RND then YES = "*Y*" if yes, blank (= NO)	1
Name of the Constituent Element	51X	6-56	O	IF FINISHED: Name of Active Ingredient contained in the dosage form IF ACTIVE PHARMACEUTICAL INGREDIENT/BULK DRUG SUBSTANCE: name of the Active Pharmaceutical Ingredient (API)	1, 2 3
Quantity of Constituent Element	12N	57-68	O	IF FINISHED – amount of active ingredient per dose if applicable IF API/BULK DRUG SUBSTANCE: total volume of API 2 decimal places are implied	1, 2 3
Unit of Measure (Constituent Element)	5AN	69-73	O	IF FINISHED: Unit of measure for Quantity of Constituent Element IF API/BULK DRUG SUBSTANCE: Unit of measure for Quantity of Constituent Element	1, 2 3
Percent of Constituent Element	7N	74-80	O	IF FINISHED Product - % of active ingredient in the product if applicable. IF API/BULK Drug Substance – Percent of the Constituent Element = percent identification of the API. 4 decimal places are implied.	1, 3, 4,

<u>Note 1</u>

IF Government Agency Program Code = DRU
AND If Government Agency Processing Code = PRE or OTC or INV or RND
THEN Constituent Active Ingredient Qualifier <u>and</u> Name of the Constituent Element are entered.

Note 2

*** Rules for **Finished Dosage Form Drugs** ***

IF PG01 Intended Use Code =

080.012 Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application

130.000 For Consumer Use as a Non- Food Product – Over the Counter (OTC)

OR

155.009 Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)

OR

180.009 Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos

OR

180.017 Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal

OR

180.018 Chemical for research and development of a pharmaceutical product – investigational use in animals

OR

180.026 Finished drug intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements

OR

920.000, US Goods Returned

OR

980.000 For Other Use: (APIs or Finished Drugs not elsewhere classified)

THEN:

Either the quantity and Unit of Measurement are entered **OR** the Percent Constituent Element is entered.

MAY REPEAT PG04 for EACH Active Pharmaceutical Ingredient in the Finished Dosage form

Example1: Ibuprofen, 200mg tablets
Name of the Constituent Element = Ibuprofen
Quantity of Constituent Element = 200 and Unit of Measure = milligrams

Example2: Anti-perspirant Deodorant
Name of the Constituent Element = aluminum zirconium tetrachlorohydrex
Percent of Constituent Element 18.2% (entered as 0182000)

Note 3

*** Rules for **Active Pharmaceutical Ingredients** (API) ***

IF PG01 Intended Use Code =

150.007 Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product

OR

150.013 Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding

OR

150.017 Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
OR
180.009 Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos
OR
180.017 Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal use
OR
180.018 Chemical for research and development of a pharmaceutical product – investigational use in animals
OR
180.026, Finished drug or API intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements
OR
920.000 US Goods Returned
OR
980.000 For Other Use: (APIs or Finished Drugs not elsewhere classified)

THEN
The quantity, Unit of Measurement and the Percent Constituent Element are entered.

Name of the Constituent Element = Active Pharmaceutical Ingredient name
Quantity of Constituent Element = Total Amount (by Unit of Measure) of the Active Pharmaceutical Ingredient
Unit of Measure = base unit of measure weight/volume (Use PG26 Base Unit Table)
Percent of Constituent Element = percent identification of the Active Pharmaceutical Ingredient.

Example: Ephedrine Hydrochloride 99%, USP, 2 – 25 KG drums
Name of the Constituent Element = Ephedrine HCl
Quantity of Constituent Element = 50 and Unit of Measure = KG

Note 4

Examples of Percentages:

1000000	=	100%
0990000	=	99%
0090000	=	9%
0009000	=	.9%
0000900	=	.09%
0000090	=	.009%
0000009	=	.0009%

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) -other than the CBP Country of Origin – for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix C shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time.**

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	Mandatory valid values are 30 (Country of Source) or 39 (Country of Production). 294 (Country of Refusal) if previously refused. There would be at least one PG06 with source type code of 30 or 39. If previously refused, then provide another PG06 with source type code 294.	1
Country Code	2X	8-9	M	Country of production or source is required for Drugs.	2

Note 1

Source Type Codes and their descriptions can be found in CBP's Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from CBP's Appendix B (ISO Country and Currency Codes) in the ACE ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is an optional PGA input record that provides data pertaining to Trade or Brand Name for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix C shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time.**

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	“PG”	
Record Type	2N	3-4	M	“07”	
Trade Name/Brand Name	35X	5-39	O	If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code ‘TBN’.	

Record Identifier PG10 (Product Characteristics)

This is a mandatory PGA input record that allows for reporting codes that provide additional characteristics of a product identified by Product Code Number in PG02, not reported elsewhere in the PG Message Set.

Using a Drug example, Appendix C shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time.**

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“10”	
Commodity Characteristic Description	57X	24-80	M	This should be Invoice Description NOT product code description. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Drugs, this is a mandatory PGA input record, requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code and Entity number are optional data elements, but they are listed as conditional because If opting to transmit Entity Identification Code then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF.	1,2,
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 16 (DUNS #) or 47 (FEI #). Mandatory, if Entity Number is entered.	3
Entity Number	15X	11-25	C	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	3
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code 'ENA'. See validation criteria below.	3
Entity Address 1	23X	58-80	M	The address of the entity is required. See validation criteria below. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code 'AD1'.	3

Note 1

Entity Role Codes and their descriptions can be found in CBP's Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Drugs Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods (Final producer for the final drug product). If the product is a bulk API, use "MF" as the Entity Role Code (rather than "GD" – Producer of API); If the product is in finished form, provide MF of final product .
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party

§ Same Role Code cannot be entered more than once.

Note 2
List of Entity Role codes **optional** to FDA Drugs Message Sets is below. By providing these optional data elements when needed, will assist in an expedited review of the entry:

Data Element	Code	Description
Entity Role Codes	SPO	Sponsor (New) – if different then MF or FD1
	GD	Producer (Producer of the API*)

*API – Active Pharmaceutical Ingredient

*** Rules for Finished Dosage Form Drugs ***
IF PG01 Intended Use Code =
080.012 Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application OR
130.000 For Consumer Use as a Non- Food Product – Over the Counter (OTC) OR
980.000 For Other Use: (APIs or Finished Drugs not elsewhere classified)
THEN: must include one MF and may include one or more GD

REPEAT GD for EACH Active Pharmaceutical Ingredient in the dosage form

List of Entity Role codes optional to FDA Drugs Message Sets:

Data Element	Code	Description
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Note 3

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Drug Message Sets is below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 4 to 10 digits	4-10N

FDA SELECTION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA/CDER prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to10 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code 'AD2'.	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	
Entity City	21X	42-62	M	City of the entity. If Entity City requires additional space, continue in a PG60 record with Qualifier Code 'ECI'.	
Entity State/Province	3AN	63-65	C	State/Province of the entity.	2
Entity Country	2A	66-67	M	ISO Country Code.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2

Note 1: If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes 'AD3', 'AD4' and 'AD5' immediately under the PG20 record for the same Entity.

Note 2: Required if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides point of contact information.

For each FDA entry line, at least one PG21 is required with the individual qualifier “FD1” (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier “PK” which should be the point of contact for the filer/broker. “PK” may be sent in one of the following ways:

- under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer) *FDA preferred method
- or as a secondary PG21 to FD1 using individual qualifier “PK” (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), or
- under any other required PG19 entity as long as “PK” is the individual qualifier in PG21.

If provided, there should be only one PK per entry line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“21”	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only FD1 and PK are allowed.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code ‘INA’.	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address needs more space, continue in a PG60 record with Qualifier Code ‘EMA’.	

Record Identifier PG23 (Affirmation of Compliance)

This is a conditional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. See CBP's Appendix PGA PG23 – Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes of ACE ABI CATAIR publication.	1
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see CBP's Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) for valid codes related to certain specific Affirmation of Compliance codes.	
Filler	1X	80	C	Space fill	

Note 1

The FDA Affirmation of Compliance Codes and their descriptions are listed in the CBP's Appendix PGA (Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes) of ACE ABI CATAIR publication. The list of AoC codes applicable to FDA Drugs Message Sets is below:

*** Exemptions from providing Affirmations of Compliance ***
*** Pharmaceutical Necessities & Containers and Research & Development products do not need AofCs ***
***
For Government Program Code = DRU AND Government Processing Code =
PHN: Pharmaceutical Necessities, Containers, Inactive Pharmaceutical Ingredients and Excipients; or
RND: Research and Development
THEN PG23 is not required

*** Import For Export entries, and Personal Importations do not require AofCs ***
For Government Program Code = DRU AND Intended Use Code =

- 100.000: Importation for Personal Use; OR970.000: Import For Export

THEN PG23 is not required

When several PG23 records are included in the Message Set, the same AoC Code can be entered only once.

The list of AoC codes **conditional** to FDA Drugs Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance	DA	New Drug Application Number or	6N	IF Government Agency Program Code = DRU AND Government Agency Processing Code = 'PRE' AND Intended Use Code = 080.012, or

Code		Abbreviated New Drug Application Number or Therapeutic Biologic Application Number		150.007, THEN DA IS MANDATORY IF Government Agency Program Code = DRU AND Government Agency Processing Code = 'OTC' AND Intended Use Code = 130.000, or 150.007, 150.017, 155.009, or 920.000, THEN DA IS OPTIONAL IF Government Agency Program Code = DRU AND Government Agency Processing Code = ' 'PRE',AND Intended Use Code = 150.017, 155.009, or 920.000, THEN DA IS OPTIONAL The DA AofC includes all the previous AoC codes, NDA, ANDA and BLA.
	REG	Drug Registration Number	9N	IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'PRE' AND Intended Use Code = 080.012, or 980.000, THEN REG IS MANDATORY IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'OTC' AND Intended Use Code = 130.000, THEN REG IS MANDATORY IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'PRE' or 'OTC' AND Intended Use Code = 150.007, 150.013, 150.017, or 155.009, THEN REG IS MANDATORY IF Government Agency Program Code = DRU AND Intended Use Code = 920.000, THEN REG IS OPTIONAL
	DLS	Drug Listing Number	10N	IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'PRE', AND Intended Use Code = 080.012, or 980.000, THEN DLS IS MANDATORY unless affirmation "PLR" is declared. IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'OTC' AND Intended Use Code = 130.000, THEN DLS IS MANDATORY IF Government Agency Program Code = 'DRU' and IF Government Agency Processing Code is 'PRE', or 'OTC' AND Intended Use Code = 150.007, 150.013, 150.017, or 155.009, THEN DLS IS MANDATORY IF Government Agency Program Code = DRU AND Intended Use Code = 920.000, THEN DLS IS OPTIONAL

				The DLS AofC includes both the previous NDC and DLS AofC codes. See Note 1 below
	IND	Investigational New Drug Number	6N	IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'INV' AND Intended Use Code = 180.009, THEN IND is MANDATORY

Note 1:
When importing finished dosage drugs that are imported by a Private Label Distributor (PLD), the Manufacturer in PG19 should be the actual manufacturer of the product being imported. The DLS should be the listing of the product by the Manufacturer who is not the Private Label Distributor.

The list of AoC codes **optional** to FDA Drugs Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	ERR	Entry Review Requested	Indicator only	ERR is just used as an indicator, no data will follow
	PLR	Used to identify the shipment as a PLAIR import shipment	Indicator only	Used as an indicator, no data will follow.
	LST	Device Listing Number	Any of the following: A+6N; B+6N; C+6N; D+6N; E+6N; L+6N; Q+6N; R+6N	See IUC-AoC Mapping Table below
	PM#	Device Premarket Number	Any of the following: P+6N; N+4N, 5N, or 6N; D+6N; H+6N; K+6N; DEN+6N;	See IUC-AoC Mapping Table below
	IDE	Investigational Device Exemption Number	G+6N OR "NSR"	

The table below shows which Affirmations of Compliance are Mandatory (M), Conditional (C), or Optional (O) based on the Intended Use Code/Import Scenario:

Intended Use (see PG01 for definitions)		**Import Scenarios**	**Mandatory Affirmations**	***Conditional Affirmations***	**Optional Affirmations**
080.012		Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application	REG, DLS, DA		PLR

100.000		Importation for Personal Use			
130.000		For Consumer Use as a Non-Food Product – Over the Counter (OTC)	REG, DLS		DA
150.007		Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product	REG, DLS	DA	
150.013		Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding	REG, DLS		
150.017		Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)	REG, DLS		DA, LST, PM#, IDE
155.009		Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product).	REG, DLS		DA, LST, PM#, IDE
180.009		Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos	IND		
180.017		Chemical for research and development of a pharmaceutical product – laboratory testing only , no human/animal use			
180.018		Chemical for research and development; investigational use in animals			
180.026		Finished drug or API intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements.			
920.000		US Goods Returned			REG, DLS, DA, IND
970.000		Import for Export			
980.000		For Other Use: (APIs or Finished Drugs not elsewhere classified)	REG, DLS		

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks. Remark Type Code should be GEN.

If GEN, the PG24 is applicable to the preceding PG02. Only one PG24:GEN is allowed per PG02 (this is to avoid multiple PG24:GEN records without a guaranteed sequencing as intended by the filer).

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”24”	
Remarks Type Code	3X	5-7	O	FDA uses only GEN as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Record Identifier PG25 (Product Condition)

This is an optional PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers and if transmitted the line value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen R=Refrigerated/Chilled, D=Dry Ice H=Fresh, U=Uncontrolled P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A = product B = container C = conveyance	
Lot Number Qualifier	1AN	15	O	Code of the entity that assigned the Lot number. For Drugs the only valid value is: 1 = Manufacturer Should not be entered if more than one PG25 record is entered	
Lot Number	25X	16-40	O	The lot number that the manufacturer/ producer/grower assigned to the product.	
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays while the missing information is obtained. If entered, the value associated with the PGA line number is in whole dollars and must be entered only in the first PG25 record in the case of multiple PG25 records. If entered, it must be right-justified with preceding zeros and be	

				greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

Record Identifier PG26 (Product Packaging)

For Drugs, this is an optional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. If included, please adhere to the following rules.

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container and must be selected from the list of base units below.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present. The same unit of measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	O	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4,5
Quantity	12N	6-17	O	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays while the missing information is obtained. If entered, this is the Quantity of the packaging level and two decimal places are implied. Must be greater than zero. Entering Quantity shall require entering Packaging Qualifier and the Unit of Measure. Example: 000000000400	2,4,5
Unit of Measure (Packaging Level)	5X	18-22	O	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3,4,5

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging

Note 2

There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as “fill” and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Drug Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix D in this document.

Valid DRUG Units of Measure for the Base Unit (Last Quantity Transmitted) are limited to the chart below:

Code	Code Name
BBL	Barrel (42 Gallons Ea)
BOL	Boluses
CAP	Capsules (Dosage)
CFT	Cubic Feet
CG	Centigrams
CM	Centimeters
CM3	Cubic Centimeters
CYD	Cubic Yard
FOZ	Ounces, fluid (Volume)
FT	Feet
G	Grams
GAL	Gallons
KG	Kilograms (Weight)
KM	Kilometer
KM2	1000 Square Meters
KM3	1000 Cubic Meters
L	Liter
LB	Pounds (avdp) (Weight)
LNM	Linear Meter
M	Meter
M2	Square Meter
M3	Cubic Meter
MG	Milligrams
MCG	Micrograms
ML	Milliliters
OZ	Ounces
PCS	Pieces
PTL	Pints
QTL	Quarts
STN	Short Ton
SUP	Suppositories
T	MetricTon
TAB	Tablets
TON	Long Ton
TOZ	Ounces, Troy

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000

cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pairs may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

100 Cartons 24 Aspirin 100 tablets 325 mg

Units 1-Quantity	100
Units 1-Measure	CT
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	100
Units 3-Measure	TAB

In this case, the invoice description contains the strength of the aspirin tablets. The product quantity is listed using the "Tablets" quantity unit code.

Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival/Entry Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is Mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Port of Arrival / Entry Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Inspection/ Laboratory Testing Status	1A	5	M	A = Anticipated arrival information. If entry type = 21, then repeat PG30 and enter F = Foreign Trade Zone.	1
Anticipated Arrival / Entry date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	1
Anticipated Arrival/ Entry time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	1
Anticipated Arrival / Entry Location Code	4AN	18-21	O	Only a value of '2' (= Census Schedule D representing the CBP port codes) OR 4 (=FIRMS Code) is allowed.	
Anticipated Port of Arrival / Entry	50X	22-71	O	For valid port codes, refer to note 1.	2
Filler	8X	72-80	M	Space fill	

Note 1:

For Non-PN shipments, A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“55”	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Record Identifier PG60 (Additional Information)

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”60”	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	72X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Note 1

Valid Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	**Description**
ENA	Entity Name for PG19
AD1	Entity address Line 1 for PG19
AD2	Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Entity City for PG20
INA	Individual Name for PG21
EMA	Email Address for PG21
TBN	Trade/Brand Name for PG07

PG60 record should follow immediately after its parent. For example, a PG60:ENA record should follow PG19 and a PG60:TBN record should follow PG07.

Stand Alone Prior Notice Submission Data Elements and Values

This chapter describes the data elements and their business rules for a stand-alone Prior Notice submission. This chapter is consisting of Prior Notice Submission (801m) requirements and the PE record requirements for FDA PE/PX.

Prior Notice Non-PGA Data Elements by Mode of Transportation (See Note)

MOT	Data Elements	Mapping	Mapping - Data Elements
AIR	IATA	PE10/PE15	Carrier
	Airway Bill Number	PE10/PE15	Ref Qual Code = AWB, Ref ID Num
	Flight Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	Container Number	PG27	Container Number
	Carrier Name	PE10/PE15/PG23	AofC - CAN – Carrier Name; ; If using a PG13 record OR if the SCAC or IATA is not provided in the PE10/PE15 this AoC value is required.
OCEAN	Bill of Lading	PE10/PE15	Ref. Qual. Code 'BOL,' Bill Type Indicator 'R,' and report the Simple Bill of Lading Number in the Reference Identifier Number field
	SCAC	PE10/PE15	Carrier
	Vessel Name	PG23	AofC – VES – Vessel Name
	Voyage Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	Container Number	PG27	Container Number
	Carrier Name	PE10/PE15/PG23	AofC - CAN – Carrier Name; Name If using a PG13 record OR if the SCAC or IATA is not provided in the PE10 this AoC value is required.
LAND - Bus, Truck	Bill of Lading	PE10/PE15	Ref. Qual. Code 'BOL,' Bill Type Indicator 'R,' and report the Simple Bill of Lading Number in the Reference Identifier Number field
	Trip Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	SCAC	PE10/PE15	Carrier
	Container Number *	PG27	Container Number
	Carrier Name	PE10/PE15/PG23	AofC - CAN – Carrier Name; If using a PG13 record OR if the SCAC or IATA is not provided in the PE10 this AoC value is required.
LAND - Rail	Bill of Lading	PE10/PE15	Ref Qual Code = BOL, Ref ID Num
	Trip Number	PG23	AofC - VFT - Voyage/Flight/Trip Number

	SCAC	PE10/PE15	Filer/SCAC Code, Ref ID Num
	Rail Car Number	PG23	AofC – RNO - Rail Car Number
	Container Number *	PG27	Container Number
Express Consignment Carrier	Tracking Number	PG28	Report Express Consignment Carrier/Courier tracking number for the shipment as applicable.
	SCAC	PG28	SCAC/IATA Code
	Carrier Name	PG28 or PG23	SCAC may be entered in PG28 otherwise use PG23 AofC - CAN – Carrier Name

* if applicable

Note: The above table makes references to select **entry-level data elements** from the PE10/PE15 to provide the context and to identify from which data source FDA expects to receive a number of the required prior notice data elements for the specific modes of transportation. For additional information on the data elements found within the PE10/PE15 record, please refer to the relevant CBP documentation. This supplemental guidance document describes only **line-level data** within the structure of the FDA PG Message Set.

Food Commodity Data Elements and Values

Food commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

Table 4a – Food commodity hierarchy

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Food	FOO	Natural State Food	NSF
FDA	Food	FOO	Processed Food	PRO
FDA	Food	FOO	Animal Food **(includes pet food, medicated feed and feeds)**	FEE
FDA	Food	FOO	Additives and Colors	ADD
FDA	Food	FOO	Dietary Supplements	DSU

The following are the potential PGA records associated with submitting Prior Notice:

PG Record	Description
OI	Record Identifier (The general product description)
PG01	PGA Identifier (The shipment is regulated by the FDA program office within FDA and the Intended Use)
PG02	Product Identifier (FDA Product Code Information)
PG06	Product Origin (FDA Country of Production, Shipment, and Refusal)
PG10	Product Characteristics (Line level Item Common/Usual/Market Name Description)
PG13	License Plate Issuer [Privately Owned Vehicle (POV) Information]
PG14	License Plate Number [Privately Owned Vehicle (POV) Information]
PG19	Entity Data (Trade Entity's Transaction Role, Identification Type, Identification Number, and 1st Line of Address)
PG20	Entity Address (Continuation of Entity information including Address Line 2, City, State/Province, Country for entities provided in PG19)
PG21	Point of Contact [Individual (POC) Information, including Name, Phone Number, Email Address for trade entities]
PG23	Affirmation of Compliance [FDA's Affirmation of Compliance (AofC) Criteria including food

PG Record	Description
	facility registration and other Prior Notice information]
PG24	Remarks (Continuation of POC name as necessary)
PG25	Product Condition (Lot # of product as required by specific commodities)
PG26	Product Packaging (Packaging Qualifier And Quantity per line)
PG27	Container Information
PG28	Express Courier Tracking (Number)§
PG30	Anticipated Arrival Information
PG55	Additional Role(s) (for future use)
PG60	Additional Information
PG00	Data Substitution

§ CBP confirmed that the PE header can only be used to submit express courier tracking numbers approved by Air Cargo Advanced Screening (ACAS) pilot in the air environment. Express courier tracking numbers for PNs for food shipments in the ground/air environment are to be reported in the PG28.

Prior Notice Example

Prior Notice message set layout sample below:

Please refer to the external file: **FDA SG 2.5 Example PG Message Sets.xlsx Tab: *PN Only***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

For Prior Notice, this is a mandatory record that provides the general description of the item. This record precedes the Record Identifiers for the PGA Message Set.

Record Identifier OI (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"OI"	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, Fruit Juice	

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution

PG00 Substitution Grouping

In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Record Identifier PG01 (PGA Identifier)

For Prior Notice, this is a mandatory input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program and Processing Codes, Intended Use Code, and Disclaim information.

Record Identifier PG01 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3X	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	M	"FOO"	1
Government Agency Processing Code	3X	14-16	M	For allowed values Codes for Food see Note 1 below.	1
Intended Use Code	16X	42-57	O	N/A for FDA lines.	
Intended Use Description	21X	58-78	O		2
Correction Indicator	1X	79	O	For future use	

Note 1

See Table 4a above for the commodity for Human Food and Animal Food commodities applicable for Prior Notice.

Note2

The submission of an Intended Use Code is not a requirement for prior notice. If providing an Intended Use Code, the following are the applicable options:

CFSAN Regulated Products Import Scenario	**Intended Use Code**	**CBP Intended Use Name**
For Research Use as Human Food	**260.000**	For Research Use as Human Food
For Research Use as an Animal Food	**015.000**	For Research Use as an Animal Food
Personal Importation	**210.000**	For Personal Use as Human Food

Record Identifier PG02 (Product Identifier)

For Prior Notice, this mandatory input record is used to indicate whether or not the information being provided relates to a product (P. The Product Code Qualifier and Number can be used to provide FDA Product Code.

Record Identifier PG02 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01	
Product Code Qualifier	4X	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	The FDA Product Code must be exactly 7 characters	

Note 1

Product Code Qualifier is currently always 'FDP' for all FDA products.
Product Code Qualifiers and their descriptions can be found in CBP's Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication.

Only one Product Code Number per line is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Group Code (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

A product is subject to Prior Notice requirements if the following condition is satisfied.

if industry_code IN ('48','49', '69', '70', '71', '72')
OR if industry_code BETWEEN '01' and '46'
OR if (industry_code+class_code+group_code) in ('50A01','50B01')
OR if (industry code ='50' and class_code in ('C', 'D', 'E', 'F', 'G', 'L')
OR if (industry code ='52' and class_code = '52D'
OR if (industry_code = '54' and subclass_code in ('A','B','C','L','M','Y'))

Record Identifier PG06 (Product Origin)

For Prior Notice, this is a mandatory input record that provides data pertaining to Source Type (FDA country of production/growth and country from which the article was shipped) for the article of food. This record also provides the conditional PN data concerning the Country or Countries) who previously refused entry of the article of food. This record can be repeated to submit the countries required for PN as described in Note 1.

Record Identifier PG06 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”06”	
Source Type Code	3X	5-7	M	Source Type Code must be selected using the following logic. IF Government Agency Program Code = FOO and natural state food/feed THEN use 262 (Place of growth) ELSE use 39 (Country of Production). IF Government Agency Program Code = FOO, THEN requires CSH (Country of Shipment). If refused from other country(s), use 294.	1
Country Code	2X	8-9	M	ISO country codes are allowed. Should match the country code in PG19-PG20 record set based on the value entered for Source Type Code: Source Type Code — Entity Role Code 39 — MF 262 — DFI or FDC	2

Note 1

Source Type Code from CBP’s Appendix PGA, PG06 – Source Type Codes may be entered.
Prior Notice requires the following data elements:

1. **Country of Shipment**, Source Type Code = CSH
2. **All Natural State Human Food and Animal Food requires** the
   - **Country of Growth,** Source Type Code = 262 –the country where the article of food was grown - for fish/seafood caught outside the waters of the US = country in which the vessel who caught the fish/seafood is registered.
3. **Non-Natural State Human Food and Animal Food requires** the
   - **Country of Production**, Source Type Code = 39- the country where the article of food was made - if made from fish/seafood aboard a vessel = country in which the vessel is registered.
4. **Country of Entry Refusal**, if the article of food has been refused by other country(ies), provide the ISO country code(s) as a part of the Prior Notice submission. (Source Code Type = 294)

Note 2

ISO Country codes from CBP's Appendix B (ISO Country and Currency Codes) in the ACE ABI CATAIR must be entered.

Record Identifier PG10 (Product Characteristics)

For Prior Notice, this is a mandatory input record that provides common or usual name description of a product or component, not reported elsewhere in the PG Message Set.

Record Identifier PG10 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”10”	
Commodity Characteristic Description	57X	24-80	M	Common, market or usual name or description, NOT product code description of the product. Free form description of the item.	1

An example of the use of PG10 record is included in Appendix A of this document.

Note 1

For PN at least one common, market or usual name in PG10 MUST be provided.

Record Identifier PG13 (License Plate Issuer)

For Prior Notice, this is a conditional input record that provides data pertaining to Licenses, Permits, Certificates or Other (LPCO). For Prior Notice submission, this PG record is only required when the carrier is a privately owned vehicle and does not have a SCAC or IATA. For this situation, this PG record allows for the submission of some of the license plate information for the subject privately owned vehicle. The data elements included in this record are Issuer and location of issuer of the LPCO. If using this record, a PG14 and PG23 (Carrier Name – CAN) are mandatory.

Record Identifier PG13 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”13”	
Issuer of LPCO	35X	5-39	O	Identifies the entity that issued the LPCO. Leave blank - not required (reserved for future use)	1
LPCO Issuer - Government Geographic Code Qualifier	3A	40-42	C	The code relating to the location of the issuer of the POV license plate. Select one: Canadian Province = PR Country Code = ISO Mexican State = MS US State = US	1
Location (Country/State/Province) of Issuer of the LPCO	3A	43-45	C	Identifies the location of the issuer of the POV license plate (ex: the US, Mexico or Canadian Province/State code or Foreign Country Code). Enter the appropriate code from CBP’s Appendix B in the ACE ABI CATAIR.	1
Regional description of location of Agency Issuing the LPCO	25X	46-70	C	This description allows for the submission of a License Plate Issuer location when the Issuer is reported as an ISO and State or Province other than those from the US, Canada, or Mexico.	1
Filler	10X	71-80	M	Space fill	

Note 1

When the Carrier or the Transport Means Owner does not have SCAC or IATA, the following data requirements Prior Notice’s privately owned vehicle (POV) license plate information should be submitted using PG13 and PG14.

License Plate Number	**PG14 –** LPCO Number
License State (US)	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Province	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Country	**PG13** - LPCO Issuer - Government Geographic Code Qualifier

Record Identifier PG14 (License Plate Number)

Applicable for Prior Notice where the carrier is a privately owned vehicle, provide the Privately Owned Vehicle license plate information.

Record Identifier PG14 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”14”	
LPCO Transaction Type	1N	5	O	Leave blank - not required (reserved for future use)	
LPCO Type	3AN	6-8	C	Identifies Type Code for Privately Owned Vehicle license plate number as applicable. Use “POV” for Type	1
LPCO Number (or Name)	33X	9-41	C	Identifies the number that corresponds to the *PN Confirmation number or* Privately Owned Vehicle license plate number.	

Note 1

This information is only required in cases where the carrier is a privately owned vehicle, and PG 13 is used to report the issuer of the license plate, provide the Privately Owned Vehicle license plate information.
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Record Identifier PG19 (Entity Data)

For Prior Notice, this is a mandatory PGA input record requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code and Entity number are optional data elements, but they are listed as conditional because If opting to transmit Entity Identification Code then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3X	5-7	M	Code identifying the role of the entity being provided. For example: MF, UC	1
Entity Identification Code	3X	8-10	C	Code identifying the Entity Type is entered. For example: 16 (DUNS #), 47 (FEI #) . Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is entered. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code 'ENA'. See validation criteria below	2
Entity Address 1	23X	58-80	C	Conditional only for the Manufacturer, PN Transmitter, and/or PN Submitter entities if a Food Facility Registration number is included in PG23 . Mandatory for all other required entities. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code 'AD1'. See Note 1 and validation criteria below.	1, 2

Note 1

Entity Role Codes and their descriptions can be found in CBP's Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes **MANDATORY** to FDA Prior Notice Message Sets is below:

Data Element	***Code***	***Description***	***Condition***
Entity Role Codes[§]	PNS	PN Submitter[1, 5]	Provide DUNS, FEI number and/or full address in PG19 and PG20 or if the facility is registered you may provide the Submitter's FDA Food Facility Registration number in PG23, with the Name, City, and Country in lieu of the full address in PG19 and PG20. POC person's name, phone, email address information is required for all PN in PG21. An optional PG21 with a fax is allowed,

Data Element	Code	Description	Condition
	PNT	PN Transmitter[1, 5]	PN Transmitter is required if the PN is not transmitted by the PN Submitter. • Provide DUNS, FEI number and/or full address in PG19 and PG20 or if the facility is registered you may provide the Transmitter's FDA Food Facility Registration number in PG23, with the Name, City, and Country in lieu of the full address in PG19 and PG20 POC person's name, phone, email address information is required in PG21. An optional PG21 with a fax is allowed,
	MF[4] **-or-** FDC[4] **-or-** DFI[4]	Manufacturer[3, 5]	Provide DUNS, FEI number and/or full address in PG19 and PG20 of the manufacturer or person (if individual) as required when the food /feed is NOT in its natural state. Otherwise if you provide the AoC code PFR (manufacturer's Food Facility Registration number) in PG23, you may provide the manufacturer's Name, City, and Country in PG19 and PG20 in lieu of the full address
		FDA Consolidator[3, 5]	Full address of the firm or person (if individual) who consolidated the articles of food from the grower(s) is required when the food/feed is in its natural state and the grower(s) is/are unknown. If registered you may provide the AoC Code CFR (FDA Consolidator's Food Facility Registration number) if available in PG23
		Grower[3, 5]	Full address of the growing location of the grower or person (if individual) is required when the food/feed IS in its natural state. If registered you may provide the AoC code GFR (Grower's Food Facility Registration number) if available in PG23
	DEQ	Shipper[5]	Full address of Shipper is required for all PN. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Shipper's Food Facility Registration number if available in PG23

§ Same Role Code cannot be entered more than once.

List of Entity Role codes that are **CONDITIONALLY REQUIRED** to FDA Prior Notice Message Sets is below:

Data Element	Code	Description	Condition
	LG	Location of Goods (Secure Holding Facility for PN Purposes)	This entity is only required for PN when the article of food/feed was refused for inadequate PN and moved under CBP Supervision. This entity is the location and address where the refused food is held.
	FD1	FDA Importer (Importer of Record)	Except for T & E entries, full address of the Importer is required for all PN. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Importer's Food Facility Registration number if available in PG23.
	UC	Ultimate Consignee (Delivered to Party)[2, 3]	Except for T & E entries, full address of the UC is required for all PN. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Ultimate Consignee's Food Facility Registration number if available in PG23.
	DFP	Owner[2, 3]	Except for T & E entries, full address of the Owner is required by all PN. Provide DUNS, FEI number with full address in PG19 and PG20 and if registered you may provide the Owner's Food Facility Registration

			number in PG23.

[1] The Entity Role of Submitter and Transmitter requires the Firm/Entity info as well as a Point of Contact info which includes the Individual's Full Name, Phone Number(s), and Email Address in PG21. An optional PG21 with a fax is allowed for the Submitter and Transmitter.

[2] Ultimate Consignee (Deliver To Party – reference guidance), Importer and Owner info is not required IF the entry line product is imported for transportation and exportation, i.e. T&E entry type.

[3] The PN regulation requires **ONE** of the following:
IF the food/feed is NOT in natural state THEN Manufacturer (MF)
IF the food/feed is in natural state THEN Grower (DFI)
IF the food/feed is in natural state, and Grower is unknown THEN Consolidator (FDC)

Grower or Consolidator. For an article of food that is in its natural state, enter the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations.

[4] **Only one** of the Entity Role Codes MF/FDC/DFI is permitted. When AoC codes are entered along with one of these PG19 entity role codes, then only a PFR or FME shall be used along with MF; only a GFR may be used in conjunction with DFI; and only a CFR may be used in conjunction with FDC.

[5] Full address means the facility's street name and number; suite/unit number, as appropriate; city; Province or State as appropriate; mail code as appropriate; and country

List of Entity Role codes **MAY BE APPLICABLE** to FDA Prior Notice Message Sets is below. These codes may not be used as a substitute for the mandatory or conditional entities listed above.

Data Element	***Code***	***Description***
Entity Role Codes	PK[1]	Point of Contact (Filer/Broker Contact Information) Any other additional POC's information may be provided using the Role Code PK

[1] For role code PK, PG20 and 21 would be required in order to submit the complete address (PG19, PG20) and name (PG21) of the individual. Also, Phone, Email address (PG21) may be additionally required depending on the individual's role in the Entry process.

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Prior Notice Message Sets is below:

Data Element	***Code***	***Description***	***Length/ Class***
Entity Identification Codes[1]	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned (FEI number)	4- 10N

For PN purposes, FDA always requires Entity Name but the Entity Address 1 is optional for the Manufacturer, PN Submitter, and/or PN Transmitter entities if an associated Food Facility Registration number is included in PG23. Optionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG20 (Entity Address)

For Prior Notice, this is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used with the PG19 and may be repeated if PG19 is repeated.

Record Identifier PG20 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code ‘AD2’.	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	
Entity City	21X	42-62	M	City of the entity. If Entity City requires additional space, continue in a PG60 record with Qualifier Code ‘ECI’.	
Entity State/Province	3X	63-65	C	State/Province of the entity. See CBP’s Appendix B in the ACE ABI CATAIR for valid codes.	2
Entity Country	2A	66-67	M	ISO Country Code. See CBP’s Appendix B in the ACE ABI CATAIR for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	M	Space fill	

Note 1: If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes ‘AD3’, ‘AD4’ and ‘AD5’ immediately under the PG20 record for the same Entity.

Note 2: Required if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides point of contact information.

For all FDA lines with 801(m) data, at least two PG21 records are required with the individual qualifiers: “PNS” and PNT” (sent with the preceding PG19 and matching individual qualifier in the PG21 records). An optional PG21 with the individual qualifier “FD1” may be transmitted with the preceding PG19FD1 and PG20FD1.

FDA also highly encourages the transmission of PG21 with the individual qualifier “PK” which should be the point of contact for the filer/broker. “PK” may be sent in one of the following ways:

- under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer) *FDA preferred method
- or as a secondary PG21 to FD1 using individual qualifier “PK” (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), or
- under any other required PG19 entity as long as “PK” is the individual qualifier in PG21.

If provided, there should be only one PK per entry line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed. An optional PG21 with a fax is allowed for the Submitter and Transmitter.

Record Identifier PG21 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”21”	
Individual Qualifier	3X	5-7	M	Identify the type of party or facility the Individual represents. For example, person is associated to the PN Submitter and PN Transmitter. Only the values of “PNS”, “PNT” or “PK” are allowed.	1
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code ‘INA’.	1, 2
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	1
Email Address or fax for the Individual	35X	46-80	M	Enter the email Address or the fax number of the individual. If the Email Address needs more space, continue in a PG60 record with Qualifier Code ‘EMA’.	1

Note 1
Prior Notice regulation requires PG21 data for the Entity Roles of *PN Submitter (PNS), and PN Transmitter (PNT)*.

Other optional PG21 records with the Individual Qualifier PK (Point of Contact) may be included, as needed.

Data Element	Code	Description
Entity Role Codes	PK	Point of Contact

Note 2
Individual's Name should have the following format:
Last Name, First Name Middle Name

Record Identifier PG23 (Affirmation of Compliance)

For Prior Notice, this is a conditional or optional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”23”	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. If the merchandise is subject to BTA, use this field to report the appropriate affirmation of compliance information, not reported elsewhere. See CBP’s Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1,2
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see CBP’s Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) for valid codes related to certain specific Affirmation of Compliance codes.	1
Filler	1X	80	C	Space fill	

Note 1

The list of **CONDITIONAL** AoC codes for the FDA Prior Notice Message Set is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	FME	Food Processing Facility Registration Exemption	1A	See Appendix B at the end of this document for valid codes When food or feed is in a natural state and the entity role code DFI(Grower) or FDC (Consolidator) is entered in lieu of manufacturer, FME and food facility registration number are NOT required. Either FME or PFR is required when the Manufacturer is transmitted. If both FME and PFR are submitted, FDA will review the registration.
	RNO	Rail Car Number		Required If MOT = Rail or MOT = Containerized Rail. For multiple Rail Car Numbers, repeat

Data Element	Code	Description	Syntax	Business Rules
				PG23 as needed. If the Rail Car Number is not available, enter 'Does Not Exist'.
	CAN	Carrier Name		If using a PG13 record OR if the SCAC or IATA are not provided this AoC value is required.
	VFT	Voyage, Trip, Flight Number		If the article of food is arriving by express consignment operator or carrier and neither the PN submitter or PN transmitter is the express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number. Otherwise, VFT is required if MOT = Air, Rail, Truck or Ocean, if it exists. If the Trip Number is not available, enter 'Does Not Exist'.
	VES	Vessel Name		Required If MOT = Ocean
	PFR	Manufacturers food facility registration number	11N	Manufacturer registration number is required unless FME and Reason code is submitted or consolidator / grower role code is submitted in lieu of manufacturer for food in its natural state. If both FME and PFR are submitted, FME is not used by the FDA.

Note 2
The list of **OPTIONAL** AoC codes for the FDA Prior Notice Message Set is below:

Data Element	Code	Description	Syntax	Business Rules
	SFR	Shippers food facility registration number	11N	optional
	UFR	Ultimate consignee food facility registration number	11N	optional
	IFR	Importers food facility registration number	11N	optional
	TFR	Transmitter food facility registration number	11N	optional
	ORN	Owners food facility registration number-	11N	optional
	SRN	Submitters food facility registration number	11N	optional
	CFR	FDA Consolidator food facility registration number	11N	optional
	GFR	Growers food facility registration number	11N	optional

	LFR	Location of Goods (Holding Facility Registration Number)	11N	optional

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be GEN.

If GEN, the PG24 is applicable to the preceding PG02. Only one PG24:GEN is allowed per PG02 (this is to avoid multiple PG24:GEN records without a guaranteed sequencing as intended by the filer).

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”24”	
Remarks Type Code	3X	5-7	C	FDA uses only GEN as its valid value.	
Remarks Text	68X	13-80	C	Free form text relevant to the shipment or the commodity.	

Record Identifier PG25 (Product Condition)

For Prior Notice, this is a conditional input record that provides data pertaining to: Lot Number required by FDA regulations for Infant formula, Acidified Foods, and LACF products. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers.

Record Identifier PG25 (Temperature Qualifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”25”	
Lot Number Qualifier	1AN	15	C	Includes Lots and/or Batches. Mandatory for Infant formula, Acidified Foods, and LACF/AF products. Should not be entered if more than one PG25 record is entered. 1 = Manufacturer	
Lot Number	25X	16-40	C	The lot number that the manufacturer assigned to the product. Mandatory for Infant formula, Acidified Foods, and LACF products. Required, if more than one PG25 record is entered.	1

Note 1:

Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:

LACF and Acidified:

Industry Codes: 02-39, 41, 71, & 72
With Process Indicator Code (PIC): Acidified-I, Aseptic-F, Commercially Sterile-E

Infant Formula:

Industry Code: 40
With Class:

- C-Formula Prod (Baby)
- N-Ready to Feed Formula Product
- O-Liquid Concentrate Formula Product
- P-Powder Formula Products
- R-Infant Formula for Sample Testing (not for sale)

Record Identifier PG26 (Product Packaging)

For Prior Notice, this is a mandatory input record that provides FDA with estimated quantity of food to be shipped by describing the Packaging Qualifier, Quantity, Unit of Measure, Package Identifier, Packaging Method, Package Material, and Packaging Filler.

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	M	"Quantity of the packaging level, For example, 000000000400. Two decimal places are implied. Must be greater than zero.	2, 4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records. **Last unit transmitted must be a base unit and only one base unit is allowed.**	3, 4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Prior Notice Message Sets. Last unit transmitted must be a base unit.

Valid FDA Food Units of Measure for Packaging Containers

Code	Description
AE	Aerosol
AM	Ampoule, Non-Protected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottle crate, Bottle rack
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected, Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylnd
BR	Bar
BS	Bottle, Non-Prot Bulbous
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CB	Crate, Beer
CC	Churn
CE	Creel
CF	Coffer
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil
CO	Carboy, Non-Protected
CON	Container
CP	Carboy, Protected
CR	Crate

CS	Case
CT	Carton
CU	Cup
CV	Cover
CX	Can, Cylindrical
CY	Cylinder
CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected
DR	Drum
EN	Envelope
FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FR	Frame
GB	Bottle, Gas
HG	Hogshead
HR	Hamper
JC	Jerri can, Rectangular
JG	Jug
JR	Jar
JT	Jute bag
JY	Jerri can, Cylindrical
KEG	Keg
KIT	Kit
MB	Bag, Multi-ply
MC	Crate, Milk
MS	Sack, Multiwall
MT	Mat
NE	Unpacked Or Unpackaged
NS	Nest
NT	Net
PA	Packet
PAL	Pallet
PC	Parcel
PH	Pitcher
PK	Package
PL	Pail
PO	Pouch
PT	Pot
PU	Tray or Tray Pack

PY	Plates in Bndl/Bnch/Truss
RG	Ring
RO	Roll
SA	Sack
SC	Crate, Shallow
SD	Spindle
SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet
SU	Suitcase
SW	Shrinkwrapped
SZ	Sheets in Bndl/Bnch/Truss
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular
TN	Tin
TO	Ton
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial
VL	Bulk Liquid
VO	Bulk,Solid,Lg Particles
VP	Vacuum-packed
VQ	Bulk Liquified Gas
VR	Bulk,Solid,Granular Parti
VY	Bulk,Solid,Fine Particle
WB	Wickerbottle

Valid FDA Food Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	***Description***	***Measure Type***
BBL	Barrels (42 Gallons Ea)	Volume
BOL	Boluses	Dosage
CAR	Carats	Weight

CAP	Capsules	Dosage
CFT	Cubic Feet	Volume
CG	Centigrams	Weight
CM3	Cubic Centimeters	Volume
CYD	Cubic Yards	Volume
DOZ	Dozen	Count
DPC	Dozen Pieces	Count
DPR	Dozen Pairs	Count
FOZ	Ounces, fluid	Volume
G	Grams	Weight
GAL	Gallons (US)	Volume
GR	Gross	Count
KG	Kilograms	Weight
KM3	1,000 Cubic Meters	Volume
L	Liters	Volume
LB	Pounds (avdp)	Weight
M3	Cubic Meters	Volume
MCG	Micrograms	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
NO	Number	Count
OZ	Ounces, weight (avdp)	Weight
PCS	Pieces	Count
PRS	Pairs	Count
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
STN	Short ton (2000 LB)	Weight
T	Metric Ton	Weight
Tab	Tablets	Dosage
TON	Long Ton (2240 LB)	Weight
TOZ	Ounces, Troy or Apoth	Weight

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:
Product: 1000 cases of mineral water, 24/12 ounce bottles in each case
Packaging Qualifier =1: 1000 CS (Case)
Packaging Qualifier =2: 24 BO (Bottle, Non-protected, Cyl)
Packaging Qualifier =3: 12 FOZ (Ounces, fluid)

Record Identifier PG27 (Container Information)

For Prior Notice, this is a conditional PGA input record that provides data pertaining to the Shipping Container Number. Data provided should match the Container Number info included in the Bill of Lading. This record is repeatable.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"27"	
Container Number (Equipment ID)	20AN	5-24	C	The number of the shipping container (CNO) as entered in the Bill of Lading based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land, the container number(s) is required for prior notice.	
Container Number (Equipment ID)	20AN	28-47	C	The number of the shipping container (CNO) as entered in the Bill of Lading based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land, the container number(s) is required for prior notice.	
Container Number (Equipment ID)	20AN	51-70	C	The number of the shipping container (CNO) as entered in the Bill of Lading based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land, the container number(s) is required for prior notice.	
Filler	7X	74-80	M	Space fill	

Record Identifier PG28 (Express Courier Tracking Number)

For Prior Notice if the Mode of Transportation is mail or express courier then Package Tracking Number Code and Package Tracking Number are conditionally required, i.e. may be submitted in PG28 in lieu of the airway bill or bill of lading and in lieu of the flight number in PG23.

Record Identifier PG28 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"28"	
Package Tracking Number Code	4AN	17-20	C	• Enter SCAC or an AWB prefix for Express Consignment Carrier/Courier. For those express consignment carriers without a SCAC or an AWB prefix, leave blank & enter carrier name in PG23	1
Package Tracking Number	50AN	21-70	C	Tracking numbers used by Express Consignment Carrier	1

Note 1:

If the article of food is arriving by express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), and in lieu of the flight number in PG23.

Record Identifier PG30 (Anticipated Arrival Info and Port of Arrival)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival Information at this time.

For Prior Notice, this is a mandatory PGA input record, with status code A in position 5, that provides data pertaining to the date, time and location of anticipated arrival information for FDA BTA.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date, time and location of arrival is Mandatory.

Record Identifier PG30 (Port of Arrival / Entry Information)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”30”	
Inspection/ Laboratory Testing Status	1A	5	M	A = Anticipated arrival information.	1
Anticipated Arrival / Entry date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	1
Anticipated Arrival/ Entry time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	1
Arrival / Entry Location Code	4AN	18-21	M	Location type code from CBP’s Appendix PGA; only the value of 2 (= Schedule D Port codes) is allowed.	
Anticipated Port of Arrival / Entry	50X	22-71	M	For valid port codes, refer to note 3.	2,
Filler	9X	72-80	M	Space fill	

Note 1:

For PN shipments, A = Anticipated Arrival Date and Time at the Anticipated Port of Arrival.

Port of Arrival:
21 CFR 1.276 (b)
(11) **Port of arrival** means the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).

Note 2:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Roles)

For Prior Notice, this is an optional input record used to provide additional roles performed by an entity or individual identified in PG19.

Record not supported by FDA at this time

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG	
Record Type	2N	3-4	M	Must always be 55	
Entity Role Code	3AN	5-7	C	Additional role of the entity.	
Entity Role Code	3AN	8-10	C	Additional role of the entity.	
Entity Role Code	3AN	11-13	C	Additional role of the entity.	
Entity Role Code	3AN	14-16	C	Additional role of the entity.	
Entity Role Code	3AN	17-19	C	Additional role of the entity.	
Entity Role Code	3AN	20-22	C	Additional role of the entity.	
Entity Role Code	3AN	23-25	C	Additional role of the entity.	
Entity Role Code	3AN	26-28	C	Additional role of the entity.	
Entity Role Code	3AN	29-31	C	Additional role of the entity.	
Entity Role Code	3AN	32-34	C	Additional role of the entity.	
Filler	46X	35-80	M	Space fill.	

Record Identifier PG60 (Additional Information)

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”60”	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	72X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Note 1

Valid Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	**Description**
ENA	Entity Name for PG19
AD1	Entity address Line 1 for PG19
AD2	Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Entity City for PG20
INA	Individual Name for PG21
EMA	Email Address for PG21
TBN	Trade/Brand Name for PG07

PG60 record should follow immediately after its parent. For example, a PG60:ENA record should follow PG19 and a PG60:TBN record should follow PG07.

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping

In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Food Commodity Combined Entry Submission - Data Elements and Values

In this scenario both 801a and 801m data elements will be submitted as a single message for an Entry.
Food commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message.

Table 4b – Food commodity hierarchy

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Food	FOO	Natural State Food	NSF
FDA	Food	FOO	Processed Food	PRO
FDA	Food	FOO	Animal Food (includes pet food, medicated feed and feeds)	FEE
FDA	Food	FOO	Additives and Colors	ADD
FDA	Food	FOO	Dietary Supplements	DSU

This chapter describes the data elements and their business rules for a 801A entry, with the Government Agency Program Code = 'FOO', which may be subject to PN regulations. To satisfy the PN requirements in a combined entry (801a and 801m), a PG14 record may be included in the combined entry in addition to all applicable PG records described in this chapter.

The following are the potential PGA records associated with submitting Foods with PN processing:

PG Record	Description
OI	Record Identifier (The commercial description of the shipment is provided)
PG01	PGA Identifier (The shipment is regulated by the FDA program office within FDA and the intended use is provided)
PG02	Product Identifier (The item type and the FDA Product Code details are provided)
PG05	Scientific Genus Name (Optional information related to the scientific species name and code)
PG06	Product Origin (FDA Country of Production, Shipment, and Refusal)
PG07	Product Trade Name (Conditional submission of product market name)
PG10	Product Characteristics (Line level item common/usual name)
PG13	License Plate Issuer [Privately Owned Vehicle (POV) Information]
PG14	License Plate Number [Privately Owned Vehicle (POV) Information]
PG19	Entity Data (Trade entity's Transaction Role, Identification Type, Identification Number, and 1st line of address)
PG20	Entity Address (Continuation of Entity information including Address line 2, City, State/Province, Country for entities provided in PG19)
PG21	Point of Contact [Individual (POC) Information including Name, Phone Number, Email address for trade entities]
PG23	Affirmation of Compliance [FDA's Affirmation of Compliance (AofC) Criteria including food facility registration, specific PN information, and other food related codes]
PG24	Remarks (Continuation of POC name as necessary)
PG25	Product Condition (Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided)
PG26	Product Packaging (Packaging qualifier and quantity of the shipment are provided)
PG27	Container Number
PG28	Express Courier Tracking (Number) and Can Dimensions(LACF Only) **§**
PG30	Anticipated Arrival Information
PG55	Additional roles performed by entity or individual (future use)
PG60	Additional Information
PG00	Data Substitution

§ CBP confirmed that the SE header can only be used to submit express courier tracking numbers in the air environment. Express courier tracking numbers for PNs for food shipments in the ground environment are to be reported in the PG28.

Prior Notice Non-PGA Data Elements by Mode of Transportation (See Note)

MOT	Required Data Elements	Mapping	Mapping - Data Elements
AIR	IATA	SE15	Carrier
	Airway Bill Number	SE15	Ref Qual Code = AWB, Ref ID Num
	Flight Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	Container Number	PG27	Container Number
	Carrier Name	PG23	AofC - CAN - Carrier Name
OCEAN	Bill of Lading	SE15	Ref. Qual. Code 'BIL,' Bill Type Indicator 'R,' and report the Simple Bill of Lading Number in the Reference Identifier Number field
	Vessel Name	PG23	AofC – VES – Vessel Name
	Voyage Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	Container Number	PG27	Container Number
	Carrier Name	PG23	AofC - CAN - Carrier Name
LAND - Bus, Truck	Bill of Lading	SE15	Ref. Qual. Code 'BIL,' Bill Type Indicator 'R,' and report the Simple Bill of Lading Number in the Reference Identifier Number field
	Trip Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	SCAC	SE15	Carrier
	Container Number *	PG27	Container Number
	Carrier Name	PG23	AofC - CAN - Carrier Name
LAND - Rail	Bill of Lading	SE15	Ref Qual Code = BIL, Ref ID Num
	Trip Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	SCAC	SE15	Filer/SCAC Code, Ref ID Num
	Rail Car Number	PG23	AofC – RNO - Rail Car Number
	Container Number *	PG27	Container Number
Express Consignment Carrier	Tracking Number	PG28	Report Express Consignment Carrier/Courier tracking number for the shipment as applicable.
	Carrier Name	PG28 or PG23	SCAC may be entered in PG28 otherwise use PG23 AofC - CAN – Carrier Name

* if applicable

Note: The above table makes references to select entry-level data elements from the SE15 to provide the context and to identify from which data source FDA expects to receive a number of the required prior notice data elements for the specific modes of transportation. For additional information on the data elements found within the SE15 record, please refer to the relevant CBP documentation. This supplemental guidance document describes only line-level data within the structure of the FDA PG Message Set.

Prior Notice Combined Entry Example

Prior Notice Combined Entry message set layout sample below:

Please refer to the external file: **FDA SG 2.5 Example PG Message Sets.xlsx Tab: *FOO+PN***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the general commercial description of the item. This record precedes the Record Identifiers for the PGA Message Set.

Record Identifier OI					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"OI"	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, NATURE'S FINEST REAL FRUIT JUICE, 12 OUNCE BOTTLES	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Intended Use Code, Intended Use Description, and Disclaimer. The Intended Use Code allows FDA to identify whether the imported commodity is restricted by a consumption allowance or not.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"FOO"	1
Government Agency Processing Code	3AN	14-16	C	Allowed values: NSF, PRO, FEE, ADD, DSU	1
Intended Use Code	16X	42-57	O		2
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	

Refer to Table 4b above for commodity type and sub-type for Food.

Note 1
If the product is Disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code, Government Agency Processing are mandatory.

Note 2
The submission of an Intended Use Code is not a requirement for prior notice. . If providing an Intended Use Code, the following are the applicable options:

CFSAN Regulated Products Import Scenario	**Intended Use Code**	**CBP Intended Use Name**
For Research Use as Human Food	**260.000**	For Research Use as Human Food
For Research Use as an Animal Food	**015.000**	For Research Use as an Animal Food
Personal Importation	**210.000**	For Personal Use as Human Food

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Note 1

Product Code Qualifiers and their descriptions can be found in CBP's Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Food commodity, this is currently always 'FDP' for all FDA products.

Only one Product Code Number per line is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Group Code (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

A product is subject to Prior Notice requirements if the following condition is satisfied.

if industry_code IN ('48','49', '69', '70', '71', '72')
OR if industry_code BETWEEN '01' and '46'
OR if (industry_code+class_code+group_code) in ('50A01','50B01')
OR if (industry code ='50' and class_code in ('C', 'D', 'E', 'F', 'G', 'L')
OR if (industry code ='52' and class_code = '52D'
OR if (industry_code = '54' and subclass_code in ('A','B','C','L','M','Y'))

Record Identifier PG05 (Scientific Genus Names)

This is an optional PGA input record that provides data pertaining to Scientific Genus Names, Scientific Species, Scientific Sub Species Name, Scientific Species Code, and FWS Description Code.

Record Identifier PG05 (Scientific Genus Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“05”	
Scientific Genus Name	22X	5-26	O	Scientific Genus Name of the merchandise being entered.	
Scientific Species Name	22X	27-48	O	Scientific Species Name of the merchandise being entered.	
Scientific Sub Species Name	18X	49-66	O	Scientific Sub Species Name of the merchandise being entered.	

Record Identifier PG06 (Product Origin)

For Prior Notice, this is a mandatory input record that provides data pertaining to Source Type (FDA country of production/growth and country from which the article was shipped) for the article of food. This record also provides the conditional PN data concerning the Country or Countries) who previously refused entry of the article of food. This record can be repeated to submit the countries required for PN as described in Note 1.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	Source Type Code must be selected using the following logic: IF Government Agency Program Code = FOO and natural state food / feed THEN use 262 (Place of growth) ELSE use 39 (Country of Production). IF Government Agency Program Code = FOO, THEN requires CSH (Country of Shipment). IF refused from other country(s), use 294.	1
Country Code	2X	8-9	M	Foods require the harvesting or production location of the product. Should match the country code in PG19-PG20 record set based on the value entered for Source Type Code: Source Type Code — Entity Role Code 39 — MF 262 — DFI or FDC	2

Note 1
Source Type Code from CBP's Appendix PGA, PG06 – Source Type Codes may be entered.
Prior Notice requires the following data elements:

Country of Shipment, Source Type Code = CSH (required for Prior Notice)
All Natural State Human Food and Animal Food requires the

- **Country of Growth,** Source Type Code = 262 - if made from fish/seafood aboard a vessel = country in which the vessel is registered.

Non-Natural State Human Food and Animal Food requires the

- **Country of Production**, Source Type Code = 39- if made from fish/seafood aboard a vessel = country in which the vessel is registered.

Country of Entry Refusal, if the article of food has been refused by other country(ies), provide the ISO country code(s) and. (Source Code Type = 294)

Note 2
ISO Country codes from CBP's Appendix B (ISO Country and Currency Codes) in the ACE ABI CATAIR must be entered.

Record Identifier PG07 (Product Trade Names)

This is an optional PGA input record that provides data pertaining to Trade or Brand Name.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“07”	
Trade Name/Brand Name	35X	5-39	O	Market, Trade, or Brand Name that describes the food or feed product at each line level. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code ‘TBN’.	

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Record Identifier PG10 (Product Characteristics)

For Food, this is a mandatory PGA input record that allows for importer to report the description of the product at the line level to capture the information currently collected in multiple OI records.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“10”	
Commodity Characteristic Description	57X	24-80	M	Common, market or usual name or description, NOT product code description of the product. Free form description of the item.	1

Record Identifier PG13 (License Plate Issuer)

For Prior Notice, this is a conditional input record that provides data pertaining to Licenses, Permits, Certificates or Other (LPCO). For Prior Notice submission, this PG record is only required when the carrier is a privately owned vehicle and does not have a SCAC or IATA. For this situation, this PG record allows for the submission of some of the license plate information for the subject privately owned vehicle. The data elements included in this record are Issuer and location of issuer of the LPCO. If using this record, a PG14 and PG23 (Carrier Name – CAN) are mandatory.

Record Identifier PG13 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”13”	
Issuer of LPCO	35X	5-39	O	Identifies the entity that issued the LPCO.	1
LPCO Issuer - Government Geographic Code Qualifier	3A	40-42	C	The code relating to the location of the issuer of the POV license plate. Select one: Canadian Province = PR Country Code = ISO Mexican State = MS US State = US	1
Location (Country/State/Province) of Issuer of the LPCO	3A	43-45	C	Identifies the location of the issuer of the POV license plate (ex: the US, Mexico or Canadian Province/State code or Foreign Country Code). Enter the appropriate code from CBP’s Appendix B in the ACE ABI CATAIR.	1
Regional description of location of Agency Issuing the LPCO	25X	46-70	C	This description allows for the submission of a License Plate Issuer location when the Issuer is reported as an ISO and State or Province other than those from the US, Canada, or Mexico.	1
Filler	10X	71-80	M	Space fill	

Note 1

When the Carrier or the Transport Means Owner does not have SCAC or IATA, the following data requirements Prior Notice’s privately owned vehicle (POV) license plate information should be submitted using PG13 and PG14.

License Plate Number	**PG14 –** LPCO Number
License State (US)	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Province	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Country	**PG13** - LPCO Issuer - Government Geographic Code Qualifier

Record Identifier PG14 (License Plate Number)

As applicable for Prior Notice where the carrier is a privately owned vehicle, provide the Privately Owned Vehicle license plate information.

Record Identifier PG14 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”14”	
LPCO Transaction Type	1N	5	O	Leave blank - not required (reserved for future use)	
LPCO Type	3AN	6-8	C	Identifies Type Code for Privately Owned Vehicle license plate number as applicable. Use “POV” for Type	1
LPCO Number (or Name)	33X	9-41	C	Privately Owned Vehicle license plate number.	

Note 1

This information is only required in cases where the carrier is a privately owned vehicle, and PG 13 is used to report the issuer of the license plate, provide the Privately Owned Vehicle license plate information.

Record Identifier PG19 (Entity Data)

For Foods, this is a mandatory PGA input record requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code and Entity number are optional data elements, but they are listed as conditional because If opting to transmit Entity Identification Code then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3X	5-7	M	Code identifying the role of the entity being provided. For example: MF, UC	1
Entity Identification Code	3X	8-10	C	Code identifying the Entity Type is entered. For example: 16 (DUNS #), 47 (FEI #) . Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is entered. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code 'ENA'. See validation criteria below.	2
Entity Address 1	23X	58-80	C	Conditional only for the PN Transmitter and PN Submitter entities if a Food Facility Registration number is included in PG23. Mandatory for all other required entities. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code 'AD1'. See Note 1 for validation criteria below.	1, 2

Note 1

Entity Role Codes and their descriptions can be found in CBP's Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes **MANDATORY** to FDA Prior Notice Message Sets is below:

Data Element	***Code***	***Description***	***Condition***
Entity Role Codes[§]	PNS	PN Submitter[1, 5]	Provide DUNS, FEI number and/or full address in PG19 and PG20 or if the facility is registered you may provide the Submitter's FDA Food Facility Registration number in PG23, with the Name, City, and Country in lieu of the full address in PG19 and PG20. POC person's name, phone, email address information is required for all PN in PG21. An optional PG21 with a fax is allowed.

Data Element	Code	Description	Condition
	PNT	PN Transmitter[1, 5]	PN Transmitter is required if the PN is not transmitted by the PN Submitter. • Provide DUNS, FEI number and/or full address in PG19 and PG20 or if the facility is registered you may provide the Transmitter's FDA Food Facility Registration number in PG23, with the Name, City, and Country in lieu of the full address in PG19 and PG20 POC person's name, phone, email address information is required in PG21. An optional PG21 with a fax is allowed.
	MF[4] **-or-** FDC[4] **-or-** DFI[4]	Manufacturer[3, 5]	Provide DUNS, FEI number and/or full address in PG19 and PG20 of the manufacturer or person (if individual) as required when the food /feed is NOT in its natural state. Although the PN submission allows you to provide the manufacturer's Food Facility Registration number in PG23, and the manufacturer's Name, City, and Country in PG19 and PG20 in lieu of the full address, the full address is required to satisfy FDA 801(a) requirements.
		FDA Consolidator[3, 5]	Full address of the firm or person (if individual) who consolidated the articles of food from the grower(s) is required when the food/feed is in its natural state and the grower(s) is/are unknown. If registered you may provide the FDA Consolidator's Food Facility Registration number if available in PG23
		Grower[3, 5]	Full address of the growing location of the grower or person (if individual) is required when the food/feed IS in its natural state. If registered you may provide the Grower's Food Facility Registration number if available in PG23
	DEQ	Shipper[5]	Full address of Shipper is required for all PN. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Shipper's Food Facility Registration number if available in PG23
	FD1	FDA Importer 1 (Importer of Record)	Full address of the Importer is required for all combined entries. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Importer's Food Facility Registration number if available in PG23. POC person's name, phone, email address information is required in PG21. An optional PG21 with a fax is allowed.
	DFP	Owner[2,]	Full address of the Owner is required for all PN. Provide DUNS, FEI number with full address in PG19 and PG20 and if registered you may provide the Owner's Food Facility Registration number in

Data Element	Code	Description	Condition
			PG23.
	UC	Ultimate Consignee (Delivered to Party)[2,]	Full address of the UC is required for all PN and entries. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Ultimate Consignee's Food Facility Registration number if available in PG23

§ Same Role Code cannot be entered more than once.

[1] The Entity Role of Submitter and Transmitter require the Firm/Entity info as well as a Point of Contact info which includes the Individual's Full Name, Phone Number(s), and Email Address in PG21. POC person's name, phone, email address information is required for all PN in PG21. An optional PG21 with a fax is allowed.

[2] Ultimate Consignee (Deliver To Party – reference guidance) and Owner info is not required IF the entry line product is imported for transportation and exportation, i.e. T&E entry type.

Even though Title 19 141.19 (CBP) addresses - Consignee -, Title 21, Requires Prior Notice information about the - Ultimate Consignee - and Title 19 (CBP) defines - Ultimate Consignee -, FDA acknowledges that these terms cause confusion and would like to simplify and harmonize said data elements under the ACE environment.

Hence, the FDA has elected to utilize the data element --- "Deliver to Party" ---, U.S party that physically receives the good(s). The FDA's PG Message Set will, therefore, incorporate the deliver to party as issued in the ITDS Standard Data Set under the auspices of the ITDS Board of Directors. FDA interprets the Prior Notice requirement for ultimate consignee to be synonymous with the deliver to party.

[3] The PN regulation requires **ONE** of the following:
IF the food/feed is NOT in natural state THEN Manufacturer
IF the food/feed is in natural state THEN Grower
IF the food/feed is in natural state, and grower is unknown THEN Consolidator

Grower or Consolidator. For an article of food that is in its natural state, enter the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations.

[4] **Only one** of the Entity Role Codes MF/FDC/DFI is permitted. If AoC codes are entered along with one of these PG19 entity role codes, then only a PFR or FME shall be used along with MF; only a GFR may be used in conjunction with DFI; and only a CFR may be used in conjunction with FDC.

[5] Full address means the facility's street name and number; suite/unit number, as appropriate; city; Province or State as appropriate; mail code as appropriate; and country
List of Entity Role codes that are **CONDITIONALLY REQUIRED** to FDA Prior Notice Message Sets is below:

Data Element	Code	Description	Condition
Entity Role			

Codes	LG	Location of Goods (Secure Holding Facility for PN Purposes)	This entity is only required for PN when the article of food/feed was refused for inadequate PN and moved under CBP Supervision. This entity is the location and address where the refused food is held.
	FSV	Foreign Supplier Verification Program Importer	These data elements relate to the Foreign Supplier Verification Program (FSVP) and will not be utilized/accepted until May 30, 2017. IF GOVT Agency program code is FOO and processing code is NSF, PRO, ADD, DSU, FEE, THEN the following FSVP-related details will be mandatory for all FDA FOO lines unless Industry Codes 16 or 32 are present in PG02: 1. DUNS#, Firm Name, Firm Address1 are required in PG19; 2. All the elements, except Apt#, are required in PG20 AND 3. Qualifier Code=FSV and eMail address are required in PG21; individual's name and tel# are optional in PG21. If line item is a food and the above items are not transmitted as above, the entry will be rejected by CBP, **unless** an exemption is declared in the Affirmations of Compliance using either of the AoC codes FSX (FSVP Exempt) or RNE (Research and Evaluation).

List of Entity Role codes **optional to** FDA Prior Notice Message Sets is below. These codes may not be used as a substitute for the mandatory or conditional entities listed above.

Data Element	*Code*	*Description*
Entity Role Codes	PK[1]	Point of Contact (Filer/Broker Contact Information)

Note 2
Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Prior Notice Message Sets is below:

Data Element	*Code*	*Description*	*Length/ Class*
Entity Identification Codes[1]	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned (FEI number)	4- 10N

For PN (801m) purposes, FDA always requires Entity Name but the Entity Address 1 for Manufacturer, PN Submitter and PN Transmitter is optional if an Food Facility Registration number is included in PG23. However, for Manufacturer, Entity Address 1 is required to satisfy 801a regulations. Optionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when additional address for the entity needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code 'AD2'.	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	
Entity City	21X	42-62	M	For example, SUGARLAND. If Entity City requires additional space, continue in a PG60 record with Qualifier Code 'ECI'.	
Entity State/Province	3AN	63-65	C	For example, TX.	2
Entity Country	2A	66-67	M	For example, US.	
Entity Zip/Postal Code	9X	68-76	C	For example, 77004.	2
Filler	4X	77-80	C	Space fill	

Note 1: If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes 'AD3', 'AD4' and 'AD5' immediately under the PG20 record for the same Entity.

Note 2: Required if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides point of contact information.

For all FDA lines with combined 801(a) and 801(m) data, at least two PG21 records are required with the individual qualifiers: “PNS” and PNT” (sent with the preceding PG19 and matching individual qualifier in the PG21 records). An optional PG21 with the individual qualifier “FD1” may be transmitted with the preceding PG19FD1 and PG20FD1.

FDA also highly encourages the transmission of PG21 with the individual qualifier “PK” which should be the point of contact for the filer/broker. “PK” may be sent in one of the following ways:

- under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer) *FDA preferred method
- or as a secondary PG21 to FD1 using individual qualifier “PK” (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), or
- under any other required PG19 entity as long as “PK” is the individual qualifier in PG21.

If provided, there should be only one PK per entry line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed. An optional PG21 with a fax is allowed for the Submitter and Transmitter.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“21”	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only codes of “PNS”, “PNT”, “FD1”, “PK” and “FSV” are allowed. PG21 with qualifier code “FSV” must follow PG19 with the qualifier code “FSV”. See PG19 for the details of FSVP (Food Supplier Verification Program).	1
Individual Name	23X	8-30	C	Name of the Individual. This is optional if the Individual Qualifier = “FSV” otherwise it is mandatory. If the name will not fit, continue in a PG60 record with Qualifier Code ‘INA’.	1,2
Telephone Number of the Individual	15X	31-45	C	This is optional if the Individual Qualifier = “FSV” otherwise it is mandatory. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	1
Email Address or fax number for the Individual	35X	46-80	M	Enter the Email Address the Individual. If the Email Address needs more space, continue in a PG60 record with Qualifier Code ‘EMA’. If sending a FAX number, send an additional	1

				PG21 record with FAX.	

Note 1
Prior Notice regulation requires PG21 data for the Entity Roles of *PN Submitter (PNS), and PN Transmitter (PNT). The regulation also required PG21 data for the FDA Importer of Record, unless entry type is Inbond entry type 62 –Transportation and Exportation (T&E)*. Other condition where PG21 information is required for Prior Notice is specified in PG19 mandatory and conditional data sections.

Additionally, at least one PG21 record is required with the Individual Qualifier FD1 (FDA importer of record). Other optional PG21 records with the Individual Qualifier PK (Point of Contact) may be included, as needed.

Although the PK (filer contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record to obtain the contact information for the filer. If Importer of Record contact information is the only information is provided, it may take additional time to obtain filer information when needed..

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact

Note 2
Individual's Name should have the following format:
Last Name, First Name Middle Name

Record Identifier PG23 (Affirmation of Compliance)

This is a conditional or optional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. See CBP's Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1, 2, 3, 4, 5
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see CBP's Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) for valid codes related to certain specific Affirmation of Compliance codes.	1
Filler	1X	80	C	Space fill	

Note 1

The list of **conditional** AoC codes for the FDA food **Prior Notice** Message Set is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	FME	Food Processing Facility Registration Exemption	1A	See Appendix B at the end of this document for valid codes When food or feed is in a natural state and the entity role code DFI(Grower) or FDC (Consolidator) is entered in lieu of manufacturer, FME and food facility registration number are NOT required. Either FME or PFR is required when the Manufacturer is transmitted. If both FME and PFR are submitted, FDA will review the registration.
	RNO	Rail Car Number		Required If MOT = Rail or MOT = Containerized Rail. For multiple Rail Car Numbers, repeat PG23 as needed.

Data Element	Code	Description	Syntax	Business Rules
				If the Rail Car Number is not available, enter 'Does Not Exist'.
	CAN	Carrier Name		If using a PG13 record OR if the SCAC or IATA are not provided this AoC value is required.
	VFT	Voyage, Trip, Flight Number		If the article of food is arriving by express consignment operator or carrier and neither the PN submitter or PN transmitter is the express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number. Otherwise, VFT is required if MOT = Air, Rail, Truck or Ocean if it exists. If the Trip Number is not available, enter 'Does Not Exist'.
	VES	Vessel Name		Required If MOT = Ocean
	PFR	Manufacturers food facility registration number	11N	Manufacturer registration number is required unless FME and Reason code is submitted or consolidator / grower role code is submitted in lieu of manufacturer for food in its natural state. See Appendix B of this document for valid codes If both FME and PFR are submitted, FME is not used by the FDA.

Note 2

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The list of **optional** AoC codes for the FDA food **Prior Notice** Message Set is below:

Data Element	Code	Description	Syntax	Business Rules
	SFR	Shippers food facility registration number	11N	Optional
	UFR	Ultimate consignee food facility registration number	11N	Optional
	IFR	Importers food facility registration number	11N	Optional
	TFR	Transmitter food facility registration number	11N	Optional
	ORN	Owners food facility registration number-	11N	Optional
	SRN	Submitters food facility registration number	11N	Optional
	CFR	FDA Consolidator food facility registration number	11N	optional

Data Element	Code	Description	Syntax	Business Rules
	GFR	Growers food facility registration number	11N	optional
	LFR	Location of Goods (Holding Facility Registration Number)	11N	optional

Note 3
The list of **conditional** AoC codes for the FDA Food **(Non-PN)** Message Set is below:

Data Element	Code	Description	Syntax	Business Rules	Note
	FCE	Food Canning Establishment Number	5N- 10N	IF Government Agency Program Code = FOO AND the product is either LACF or AF THEN FCE must be entered. See Note 5 for details.	5
	SID	Schedule Identifier Number	11N	IF Government Agency Program Code = FOO AND the product is LACF or AF THEN AoC Code 'SID' must be entered. Format: CCYYMMDDnnn. See Note 5 for details.	5
	VOL	LACF/AF Volume		IF Government Agency Program Code = FOO AND the product is AF THEN VOL must be entered. See Note 5 for exceptions.	5
	FSX	PRODUCT TYPE IS FSVP EXEMPT OR LATER COMPLIANCE DATE		Indicator only. This AoC code will not be utilized/accepted until May 30, 2017. See PG19 for details on the qualifier code FSV.	
	RNE	PRODUCT IS FOR R&E (Research and Evaluation), THUS FSVP EXEMPT		Indicator only. This AoC code will not be utilized/accepted until May 30, 2017. See PG19 for details on the qualifier code FSV.	

Note 4
The list of **optional** AoC codes for the FDA Food **(Non-PN)** Message Set is below:

Data Element	Code	Description	Syntax	Business Rules	Note
	CIN	Color Identification Number	Text (30X max.)	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN CIN IS ALLOWED	
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow	
	FAP	Food Additive Petition Approval Number	6N	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN FAP IS ALLOWED	

Data Element	Code	Description	Syntax	Business Rules	Note
	FCC	French Cheese Facility Certification Number	9X or 10X	IF Government Agency Program Code = FOO AND Government Agency Processing Code = PRO THEN FCC IS ALLOWED. If length = 9, then the format should be 'NN NNN NN'; if length = 10, then the format should be 'NN NNN NNN'.	
	IBP	Indian Black Pepper Certificate	text	IF Government Agency Program Code = FOO AND Government Agency Processing Code = NSF THEN IBP IS ALLOWED	
	IFE	Import For Export	indicator only		
	PKC	Package/Can Code		IF Government Agency Program Code = FOO THEN PKC IS ALLOWED	
	AIN	Food Additive Identification Number	6N or 8N or E+7N	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN AIN IS ALLOWED	
	JIF	Juice HACCP Importer Firm	7N or 10N	IF Government Agency Program Code = FOO AND the product is HACCP THEN JIF IS ALLOWED	
	SIF	Seafood HACCP Importer Firm	7N or 10N	IF Government Agency Program Code = FOO AND the product is HACCP THEN SIF IS ALLOWED	

Note 5:

Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:

LACF and Acidified:

LACF: Industry Codes: 02-39, 41, 71, & 72 with PIC: **F** (Aseptic) and **E** (Commercially Sterile)

AF: Industry Codes: 02-39, 41, 71, & 72 with PIC: **I** (Acidified)
If the product is Low-Acid Canned Food (LACF) or Acidified Food (AF), both the AoC codes, FCE and SID must be provided; additionally, one of the following must be provided:

1. Container Measurements in PG28 **OR**
2. Container Volume AoC code VOL

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be GEN.

If GEN, the PG24 is applicable to the preceding PG02. Only one PG24:GEN is allowed per PG02 (this is to avoid multiple PG24:GEN records without a guaranteed sequencing as intended by the filer).

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”24”	
Remarks Type Code	3X	5-7	C	FDA uses only GEN as its valid value.	
Remarks Text	68X	13-80	C	Free form text relevant to the shipment or the commodity.	

Record Identifier PG25 (Product Condition)

For Food, this is a conditional PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers and the line value may be included on the first PG25 record.

For Prior Notice, this is a conditional input record that provides data pertaining to: Lot Number required by FDA regulations for Infant formula, Acidified Foods, and LACF products.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier	1AN	15	C	Code of the entity that assigned the Lot number. 1 = Manufacturer and 3 = Grower . IF Government Agency Program Code = FOO and Government Agency Processing Code = NSF THEN Lot Number Qualifier = 3 ELSE Lot Number Qualifier = 1 Should not be entered, if more than one PG25 record is entered.	
Lot Number	25X	16-40	C	The lot number that the manufacturer assigned to the product. Mandatory for Infant formula, Acidified Foods, and LACF products. Required, if more than one PG25 record is entered.	1
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product	

				in a timely manner. Failure to transmit the value may result in delays while the missing information is obtained. If entered: The value associated with the PGA line number is in whole dollars. Should be entered only in the first PG25 record in the case of multiple PG25 records. Should be right-justified with preceding zeros and be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied. IF Government Agency Program Code = 'FOO' AND IF AoC Code = 'IFE' THEN this is MANDATORY	

Note 1:

Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:

LACF and Acidified:

Industry Codes: 02-39, 41, 71, & 72
With Process Indicator Code (PIC): Acidified-**I**, Aseptic-**F**, Commercially Sterile-**E**

Infant Formula:

Industry Code: 40
With Class:

- C-Formula Prod (Baby)
- N-Ready to Feed Formula Product
- O-Liquid Concentrate Formula Product
- P-Powder Formula Products
  R-Infant Formula for Sample Testing (not for sale)

Record Identifier PG26 (Product Packaging)

For Prior Notice, this is a mandatory PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure.

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	M	Quantity of the packaging level, For example, 000000000400. Two decimal places are implied. Must be greater than zero.	2, 4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3, 4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Food Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix D in this document or to the Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Valid FDA Food Units of Measure for Packaging Containers

Code	Description
AE	Aerosol
AM	Ampoule, Non-Protected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottle crate, Bottle rack
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected, Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylnd
BR	Bar
BS	Bottle, Non-Prot Bulbous
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CB	Crate, Beer
CC	Churn
CE	Creel
CF	Coffer
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil
CO	Carboy, Non-Protected
CON	Container
CP	Carboy, Protected
CR	Crate
CS	Case
CT	Carton
CU	Cup
CV	Cover
CX	Can, Cylindrical
CY	Cylinder
CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected

DR	Drum
EN	Envelope
FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FR	Frame
GB	Bottle, Gas
HG	Hogshead
HR	Hamper
JC	Jerri can, Rectangular
JG	Jug
JR	Jar
JT	Jute bag
JY	Jerri can, Cylindrical
KEG	Keg
KIT	Kit
MB	Bag, Multi-ply
MC	Crate, Milk
MS	Sack, Multiwall
MT	Mat
NE	Unpacked Or Unpackaged
NS	Nest
NT	Net
PA	Packet
PAL	Pallet
PC	Parcel
PH	Pitcher
PK	Package
PL	Pail
PO	Pouch
PT	Pot
PU	Tray or Tray Pack
PY	Plates in Bndl/Bnch/Truss
RG	Ring
RO	Roll
SA	Sack
SC	Crate, Shallow
SD	Spindle
SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet
SU	Suitcase
SW	Shrinkwrapped
SZ	Sheets in Bndl/Bnch/Truss
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular

TN	Tin
TO	Ton
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial
VL	Bulk Liquid
VO	Bulk,Solid,Lg Particles
VP	Vacuum-packed
VQ	Bulk Liquified Gas
VR	Bulk,Solid,Granular Parti
VY	Bulk,Solid,Fine Particle
WB	Wickerbottle

Valid FDA Food Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	***Description***	***Measure Type***
BBL	Barrels (42 Gallons Ea)	Volume
BOL	Boluses	Dosage
CAR	Carats	Weight
CAP	Capsules	Dosage
CFT	Cubic Feet	Volume
CG	Centigrams	Weight
CM3	Cubic Centimeters	Volume
CYD	Cubic Yards	Volume
DOZ	Dozen	Count
DPC	Dozen Pieces	Count
DPR	Dozen Pairs	Count
FOZ	Ounces, fluid	Volume
G	Grams	Weight
GAL	Gallons (US)	Volume
GR	Gross	Count
KG	Kilograms	Weight
KM3	1,000 Cubic Meters	Volume
L	Liters	Volume
LB	Pounds (avdp)	Weight
M3	Cubic Meters	Volume
MCG	Micrograms	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
NO	Number	Count
OZ	Ounces, weight (avdp)	Weight
PCS	Pieces	Count
PRS	Pairs	Count
PTL	Pints, liquid (US)	Volume

QTL	Quarts, liquid (US)	Volume
STN	Short ton (2000 LB)	Weight
T	Metric Ton	Weight
Tab	Tablets	Dosage
TON	Long Ton (2240 LB)	Weight
TOZ	Ounces, Troy or Apoth	Weight

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:
Product: 1000 cases of mineral water, 24/12 ounce bottles in each case

Units 1-Quantity	1000
Units 1-Measure	CS
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	12
Units 3-Measure	FOZ (Last packaging level transmitted must include a base unit).

Record Identifier PG27 (Container Information)

For Prior Notice, this is a conditional PGA input record that provides data pertaining to the Shipping Container Number. Data provided should match the Container Number info included in the Bill of Lading. This record is repeatable.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“27”	
Container Number (Equipment ID)	20AN	5-24	C	The number of the shipping container (CNO) as entered in the Bill of Lading based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land; the container number(s) is required for prior notice.	
Container Number (Equipment ID)	20AN	28-47	C	The number of the shipping container (CNO) as entered in the Bill of Lading based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land, the container number(s) is required for prior notice.	
Container Number (Equipment ID)	20AN	51-70	C	The number of the shipping container (CNO) as entered in the Bill of Lading based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land, the container number(s) is required for prior notice.	
Filler	7X	74-80	M	Space fill	

Record Identifier PG28 Express Courier Tracking and Can Dimensions (Acidified and LACF)

For Acidified and Low Acid Canned Food (LACF) this is a conditional PGA input record that provides data pertaining to reporting Container Dimensions for the Food and Drug. For Prior Notice if the Mode of Transportation is mail or express courier then Package Tracking Number Code and Package Tracking Number are conditionally required, i.e. may be submitted in PG28 in lieu of the airway bill or bill of lading and in lieu of the flight number in PG23.

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Record Identifier PG28 (Tracking and/or Can Dimensions – LACF only)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"28"	
Can Dimensions #1	4N	5-8	C	The first dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the container is cylindrical, the dimensions are in diameter and height order. Container dimension information is restricted to use with acidified and low acid canned foods. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Can Dimensions #2	4N	9-12	C	The second dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the container is cylindrical, the dimensions are in diameter and height order. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Can Dimension #3	4N	13-16	C	The third dimension. If the container is rectangle, the dimension is in width, height, and length order. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Package Tracking Number Code	4AN	17-20	C	• Enter SCAC for Express Consignment Carrier/Courier. For those express consignment carriers without a SCAC, leave blank & enter carrier name in PG23	3
Package Tracking Number	50AN	21-70	C	Tracking numbers used by Express Consignment Carrier	3

Note 1:

IF Government Agency Program Code = FOO and
If the product is Low-Acid Canned Food (LACF) or Acidified Food (AF), <u>one of the following</u> must be provided:

1. Container Measurements in PG28 (either height and diameter or height/length, width and thickness **OR**
2. Container Volume (VOL) in PG23

Note 2:

If the container is rectangular, the dimensions are in width, height & length order. Each dimension is expressed as a four-digit number. The first 2 digits give the number of whole inches. The next two digits give the additional fraction of the dimension expressed as sixteenths of an inch.

E.g. 1404 x 0800 x 0608 represents 14 4/16” width, 8” height and 6 8/16” length.

If the container is cylindrical the dimensions are in diameter & height order. Each dimension is expressed as a three-digit number. The first digit gives the number of whole inches. The next two digits give the additional fraction of the dimension expressed as sixteenths of an inch.

E.g. 300 x 108 represents 3” diameter & 1 8/16” height.

Note 3:

If the article of food is arriving by express consignment operator or carrier and neither the PN submitter or PN transmitter is the express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), and in lieu of the flight number in PG23.

Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival/Entry Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date, time and location of arrival is Mandatory.

Record Identifier PG30 (Port of Arrival / Entry Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Inspection/ Laboratory Testing Status	1A	5	M	A = Anticipated arrival information.	1
Anticipated Arrival / Entry date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	1
Anticipated Arrival / Entry time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	1
Anticipated Arrival / Entry Location Code	4AN	18-21	M	Location type code from Appendix PGA; only the value of 2 (= Schedule D Port codes) is allowed.	
Anticipated Port of Arrival / Entry	50X	22-71	M	For valid port codes, refer to note 3.	2
Filler	8X	72-80	M	Space fill	

Note 1:

For PN shipments, A = Anticipated Arrival Date and Time at the Anticipated Port of Arrival.
For Non-PN shipments, A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Arrival:
21 CFR 1.276 (b)
(11) **Port of arrival** means the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

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Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“55”	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fills.	

Record Identifier PG60 (Additional Information)

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”60”	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	72X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Note 1

Valid Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	**Description**
ENA	Entity Name for PG19
AD1	Entity address Line 1 for PG19
AD2	Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Entity City for PG20
INA	Individual Name for PG21
EMA	Email Address for PG21
TBN	Trade/Brand Name for PG07

PG60 record should follow immediately after its parent. For example, a PG60:ENA record should follow PG19 and a PG60:TBN record should follow PG07.

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping

In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Non-PN Food Commodity OR PN Requirements Previously Met - Data Elements and Values

This chapter describes the data elements and their business rules for a 801A entry for Food, with the Government Agency Program Code = 'FOO', which either may not be subject to PN regulations or may have already satisfied PN data requirements. To show that the PN requirements were already satisfied, a PG14 record with the PN Conformation Number) may be included in the PG Message Set in addition to all applicable PG records described in this chapter.

In this scenario 801(a) data elements may be submitted with a PG14 record including the Prior Notice Confirmation Number. or if the Government Processing Code is CCW or if food is withdrawn from a Foreign Trade Zone (FTZ). Prior Notice Confirmation Number in PG 14 is NOT always required. Food commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Food	FOO	Natural State Food	NSF
FDA	Food	FOO	Processed Food	PRO
FDA	Food	FOO	Animal Food (includes pet food, medicated feed and feeds)	FEE
FDA	Food	FOO	Additives and Colors	ADD
FDA	Food	FOO	Dietary Supplements	DSU
FDA	Food	FOO	Ceramicware and other food contact substances	CCW

Table 4b – Food commodity hierarchy

The following are the potential PGA records associated with submitting Foods:

PG Record	Description
OI	The commercial description of the shipment is provided.
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	The item type and Product Code detail are provided.
PG05	The scientific species name and code
PG06	Source Type(origin) other than the CBP country of origin is provided
PG07	The Trade/Brand Name
PG10	Category Code

PG Record	Description
PG14	PN Confirmation Number
PG19	The entity (manufacturer, consignee, shipper, etc.) of Record's identification information is provided.
PG20	Additional address data on the entity in PG19 is provided
PG21	The entity (manufacturer, consignee, shipper, etc.) of Record's individual point of contact, phone number and email is given.
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Container Number
PG28	Can Dimensions (LACF Only)
PG30	Anticipated Arrival Information
PG55	Additional roles performed by entity or individual (future use)
PG60	Additional Information
PG00	Data Substitution

Food Example

Food message set layout sample below:

Please refer to the external file: **FDA SG 2.5 Example PG Message Sets.xlsx Tab: *FOO+PNC***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message Set.

Record Identifier OI					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“OI”	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, NATURE’S FINEST REAL FRUIT JUICE, 12 OUNCE BOTTLES	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, , Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"FOO"	1
Government Agency Processing Code	3AN	14-16	C	Allowed values: NSF, PRO, FEE, ADD, DSU,CCW	1
Intended Use Code	16X	42-57	O		2
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	"A" (= product is not regulated by this agency) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	

Refer to Table 4b above for commodity type and sub-type for Food

Note 1
If the product is to be disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code, Government Agency Processing are mandatory.

Note 2
The submission of an Intended Use Code is not a requirement for foods and food contact surfaces . If providing an Intended Use Code, the following are the applicable options:

CFSAN Regulated Products Import Scenario	**Intended Use Code**	**CBP Intended Use Name**
For Research Use as Human Food	**260.000**	For Research Use as Human Food
For Research Use as an Animal Food	**015.000**	For Research Use as an Animal Food
Personal Importation	**210.000**	For Personal Use as Human Food

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	FDP	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Note 1

Product Code Qualifiers and their descriptions can be found in CBP's Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Food commodity, this is currently always 'FDP' for all FDA products.

Only one Product Code Number per line is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Group Code (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

IF Government Agency Program Code = 'FOO' AND Government Agency Processing Code = 'CCW'
THEN PRODUCT.CODE.INDUSTRY = 52

Record Identifier PG05 (Scientific Genus Names)

This is an optional PGA input record that provides data pertaining to Scientific Genus Names, Scientific Species, Scientific Sub Species Name, and Scientific Species Code.

Record Identifier PG05 (Scientific Genus Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“05”	
Scientific Genus Name	22X	5-26	O	Scientific Genus Name of the merchandise being entered.	
Scientific Species Name	22X	27-48	O	Scientific Species Name of the merchandise being entered.	
Scientific Sub Species Name	18X	49-66	O	Scientific Sub Species Name of the merchandise being entered.	

Record Identifier PG06 (Product Origin)

This is A Mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	IF Government Agency Program Code = FOO and Government Agency Processing Code = NSF THEN Source Type Code MUST BE 262 (Place of growth) ELSE Source Type Code must be 39 (Country of Production). 294 (Country of Refusal) is Allowed. If previously refused, then trade would also provide another PG06 with source type code 294.	1
Country Code	2X	8-9	M	Foods require the harvesting or production location of the product.	2

Note 1

Source Type Codes and their descriptions can be found in CBP's Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from CBP's Appendix B (ISO Country and Currency Codes) in the ACE ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is an optional PGA input record that provides data pertaining to Trade or Brand Name.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“07”	
Trade Name/Brand Name	35X	5-39	O	Market, Trade, or Brand Name that describes the food or feed product at each line level. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code ‘TBN’.	

Record Identifier PG10 (Product Characteristics)

For Food, this is a mandatory PGA input record that allows for importer to report the description of the product at the line level to capture the information currently collected in multiple OI records.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“10”	
Commodity Characteristic Description	57X	24-80	M	Free form description (invoice description, NOT product code description) of the item. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG14 (PN Confirmation Number)

For Foods with a previously submitted prior notice, the *Prior Notice Confirmation Number* information is required.

If declaring FTZ in PG30 for Entry Type 21 OR the Government Processing Code is CCW, this record is not needed.

Record Identifier PG14 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”14”	
Transaction Type	1N	5	C	Identifies the transaction type. 1 = single use	1
Code Type	3AN	6-8	C	Identifies Type Codes for PN Confirmation Number PN Confirmation Number = PNC	1
PNC Number	33X	9-41	C	Identifies the number that corresponds to the *PN Confirmation number* This should be a 12 digit number.	1

Note 1

- Prior notice must be submitted before arrival and admission into a FTZ, prior notice is not required when the food is withdrawn from the FTZ, either as an export or for use within the U.S. However, if the food is withdrawn from the FTZ for consumption entry into the U.S., FDA must be notified and will make the admissibility decision about the consumption entry at that time.

Record Identifier PG19 (Entity Data)

For Foods, this is a mandatory PGA input record requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code and Entity number are optional data elements, but they are listed as conditional because If opting to transmit Entity Identification Code then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example: MF, DP	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example: 16 (DUNS #), 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code 'ENA'. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code 'AD1'. See validation criteria below.	2

Note 1
Entity Role Codes and their descriptions can be found in CBP's Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes **mandatory** to FDA Food Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party

§ Same Role Code cannot be entered more than once.

List of Entity Role codes **conditional** to FDA Food Message Sets is below:

Data Element	***Code***	***Description***	***Condition***
Entity Role Codes	FSV	Foreign Supplier Verification Program Importer	<u>These data elements related to the Foreign Supplier Verification Program (FSVP) and will not be utilized/accepted until May 30, 2017.</u> IF GOVT Agency program code is FOO and processing code is NSF, PRO, ADD, DSU, FEE, THEN the following FSVP-related details will be mandatory for all FDA FOO lines unless Industry Codes 16 or 32 are present in PG02:

Data Element	Code	Description	Condition
			1. DUNS#, Firm Name, Firm Address1 are required in PG19; 2. All the elements, except Apt#, are required in PG20 AND 3. Qualifier Code=FSV and eMail address are required in PG21; individual's name and tel# are optional in PG21. If line item is a food and the above items are not transmitted as above, after May 30th 2017, the entry will be rejected by CBP, **unless** an exemption is declared in the Affirmations of Compliance using either of the AoC codes FSX (FSVP Exempt) or RNE (Research and Evaluation).

Note 2

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned	4-10N

FDA SELECTION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

List of Entity Role codes optional FDA Food Message Sets is below:

Data Element	Code	Description
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code ‘AD2’.	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	
Entity City	21X	42-62	M	For example, SUGARLAND. If Entity City requires additional space, continue in a PG60 record with Qualifier Code ‘ECI’.	
Entity State/Province	3AN	63-65	C	For example, TX.	2
Entity Country	2A	66-67	M	For example, US.	
Entity Zip/Postal Code	9X	68-76	C	For example, 77004.	2
Filler	4X	77-80	C	Space fill	

Note 1: If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes ‘AD3’, ‘AD4’ and ‘AD5’ immediately under the PG20 record for the same Entity.

Note 2: Required if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides point of contact information.

For FDA lines with processing code CCW (ceramic ware and other food contact surfaces), at least one PG21 is required with the individual qualifier “FD1” (sent with the preceding PG19FD1 and PG20FD1 records).

For other processing codes, an optional PG21 with the individual qualifier “FD1” may be included with the preceding PG19FD1.

FDA also highly encourages the transmission of PG21 with the individual qualifier “PK” which should be the point of contact for the filer/broker. “PK” may be sent in one of the following ways:

- under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer) *FDA preferred method
- or as a secondary PG21 to FD1 using individual qualifier “PK” (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), or
- under any other required PG19 entity as long as “PK” is the individual qualifier in PG21.

If provided, there should be only one PK per entry line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“21”	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only “FD1”, “PK” and ‘FSV’ are allowed. PG21 with qualifier code “FSV” must follow PG19 with the qualifier code “FSV”. See PG19 for details of FSV (Food Supplier Verification Program).	1
Individual Name	23X	8-30	C	Name of the Individual. This is optional if the Individual Qualifier = “FSV” otherwise it is mandatory. If the name will not fit, continue in a PG60 record with Qualifier Code ‘INA’.	
Telephone Number of the Individual	15X	31-45	C	This is optional if the Individual Qualifier = “FSV” otherwise it is mandatory. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address needs more space, continue in a PG60 record with Qualifier Code ‘EMA’.	

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication.

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact (Filer/Broker contact information).

Record Identifier PG23 (Affirmation of Compliance)

This is a conditional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. See CBP's Appendix PGA (Food & Drug Affirmation of Compliance Codes) for valid codes.	1, 2
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see CBP's Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) for valid codes related to certain specific Affirmation of Compliance codes.	1, 2
Filler	1X	80	C	Space fill	

Note 1

The FDA Affirmation of Compliance Codes and their descriptions are listed in the Appendix PGA (Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes) of ACE ABI CATAIR publication. T

The list of AoC codes **conditional** to FDA Food Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***	***Note***
	FCE	Food Canning Establishment Number	5N-10N	IF Government Agency Program Code = FOO and the product is either LACF or AF THEN FCE must be entered. See Note 2 for details.	2
	SID	Schedule Identifier Number	11N	IF Government Agency Program Code = FOO AND the product is either LACF or AF THEN AoC Code 'SID' must be entered. Format: CCYYMMDDnnn. See Note 2 for details.	2
	VOL	LACF/AF Volume		IF Government Agency Program Code = FOO AND the product is AF THEN VOL must be entered. See Note 2 for exceptions.	2
	FSX	PRODUCT TYPE IS FSVP EXEMPT OR LATER COMPLIANCE DATE		Indicator only. This AoC code will not be utilized/accepted until May 30, 2017. See PG19 for details on the qualifier code FSV.	
	RNE	PRODUCT IS FOR R&E (Research and Evaluation), THUS FSVP EXEMPT		Indicator only. This AoC code will not be utilized/accepted until May 30, 2017. See PG19 for details on the qualifier code FSV.	

The list of AoC codes **optional** to FDA Food Message Sets is below:

Data Element	Code	Description	Syntax	Business Rules	Note
Affirmation of Compliance Code	CCC	Chinese Ceramic Ware Factory Code	6AN	IF Government Agency Program Code = FOO AND Government Agency Processing Code = CCW THEN CCC IS ALLOWED	
	CIN	Color Identification Number	text	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN CIN IS ALLOWED	
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow	
	FAP	Food Additive Petition Approval Number	6N	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN FAP IS ALLOWED	
	FCC	French Cheese Facility Certification Number	9X or 10X	IF Government Agency Program Code = FOO AND Government Agency Processing Code = PRO THEN FCC IS ALLOWED. If length = 9, then the format should be 'NN NNN NN'; if length = 10, then the format should be 'NN NNN NNN'.	
	AIN	Food Additive Identification Number	6N or 8N or E+7N	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN AIN IS ALLOWED	
	JIF	Juice HACCP Importer Firm	7N or 10N	IF Government Agency Program Code = FOO AND the product is HACCP THEN JIF IS ALLOWED	
	SIF	Seafood HACCP Importer Firm	7N or 10N	IF Government Agency Program Code = FOO AND the product is HACCP THEN SIF IS ALLOWED	
	IBP	Indian Black Pepper Certificate	text	IF Government Agency Program Code = FOO AND Government Agency Processing Code = NSF THEN IBP IS ALLOWED	
	IFE	Import For Export	indicator only		
	PKC	Package/Can Code		IF Government Agency Program Code = FOO THEN PKC IS ALLOWED	

Note 2:

Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:

LACF and Acidified:

LACF: Industry Codes: 02-39, 41, 71, & 72 with PIC: **F** (Aseptic) and **E** (Commercially Sterile)

AF: Industry Codes: 02-39, 41, 71, & 72 with PIC: **I** (Acidified)
If the product is Low-Acid Canned Food (LACF) or Acidified Food (AF), both the FCE and SID must be provided; additionally one of the following must be provided:

1. Container Measurements in PG28 **OR**
2. Container Volume AoC Code VOL

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be GEN.

If GEN, the PG24 is applicable to the preceding PG02. Only one PG24:GEN is allowed per PG02 (this is to avoid multiple PG24:GEN records without a guaranteed sequencing as intended by the filer).

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”24”	
Remarks Type Code	3X	5-7	O	FDA uses only GEN as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Record Identifier PG25 (Product Condition)

For Food, this is an optional PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers. If opting to transmit the line value, the line value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier	1AN	15	O	Code of the entity that assigned the Lot number. 1 = Manufacturer and 3 = Grower. IF Government Agency Program Code = FOO and Government Agency Processing Code = NSF THEN Lot Number Qualifier = 3 ELSE Lot Number Qualifier = 1 Should not be entered if more than one PG25 record is entered	
Lot Number	25X	16-40	O	The lot number that the manufacturer / Grower assigned to the product.	
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays while the missing information is obtained. If entered, the value associated with the PGA line number is in whole dollars. and must be entered only in the first PG25 record	

				in the case of multiple PG25 records. If entered, it must be right-justified with preceding zeros and be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

Record Identifier PG26 (Product Packaging)

For Food, this is an optional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure.

Although this is an optional record, if opting to transmit PG26 data, the Packaging Qualifier, Quantity, and Unit of Measure must all be transmitted in accordance with the following instructions:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container and must be selected from the list of base units below.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present. The same unit of measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	C	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays while the missing information is obtained. If entered, this is the Quantity of the packaging level and two decimal places are implied. Must be greater than zero. Entering Quantity shall require entering Packaging Qualifier and the Unit of Measure. Example: 000000000400	2, 4
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3, 4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2

There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as “fill” and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Food Message Sets:

Valid FDA Food Units of Measure for Packaging Containers

Code	*Description*
AE	Aerosol
AM	Ampoule, Non-Protected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottle crate, Bottle rack
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected, Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylnd
BR	Bar
BS	Bottle, Non-Prot Bulbous
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CB	Crate, Beer
CC	Churn
CE	Creel
CF	Coffer
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil
CO	Carboy, Non-Protected
CON	Container
CP	Carboy, Protected
CR	Crate
CS	Case
CT	Carton
CU	Cup
CV	Cover
CX	Can, Cylindrical
CY	Cylinder
CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected
DR	Drum
EN	Envelope

FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FR	Frame
GB	Bottle, Gas
HG	Hogshead
HR	Hamper
JC	Jerri can, Rectangular
JG	Jug
JR	Jar
JT	Jute bag
JY	Jerri can, Cylindrical
KEG	Keg
KIT	Kit
MB	Bag, Multi-ply
MC	Crate, Milk
MS	Sack, Multiwall
MT	Mat
NE	Unpacked Or Unpackaged
NS	Nest
NT	Net
PA	Packet
PAL	Pallet
PC	Parcel
PH	Pitcher
PK	Package
PL	Pail
PO	Pouch
PT	Pot
PU	Tray or Tray Pack
PY	Plates in Bndl/Bnch/Truss
RG	Ring
RO	Roll
SA	Sack
SC	Crate, Shallow
SD	Spindle
SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet
SU	Suitcase
SW	Shrinkwrapped
SZ	Sheets in Bndl/Bnch/Truss
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular
TN	Tin
TO	Ton
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial
VL	Bulk Liquid
VO	Bulk,Solid,Lg Particles
VP	Vacuum-packed

VQ	Bulk Liquified Gas
VR	Bulk,Solid,Granular Parti
VY	Bulk,Solid,Fine Particle
WB	Wickerbottle

Valid FDA Food Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	*Description*	*Measure Type*
BBL	Barrels (42 Gallons Ea)	Volume
BOL	Boluses	Dosage
CAR	Carats	Weight
CAP	Capsules	Dosage
CFT	Cubic Feet	Volume
CG	Centigrams	Weight
CM3	Cubic Centimeters	Volume
CYD	Cubic Yards	Volume
DOZ	Dozen	Count
DPC	Dozen Pieces	Count
DPR	Dozen Pairs	Count
FOZ	Ounces, fluid	Volume
G	Grams	Weight
GAL	Gallons (US)	Volume
GR	Gross	Count
KG	Kilograms	Weight
KM3	1,000 Cubic Meters	Volume
L	Liters	Volume
LB	Pounds (avdp)	Weight
M3	Cubic Meters	Volume
MCG	Micrograms	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
NO	Number	Count
OZ	Ounces, weight (avdp)	Weight
PCS	Pieces	Count
PRS	Pairs	Count
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
STN	Short ton (2000 LB)	Weight
T	Metric Ton	Weight
Tab	Tablets	Dosage
TON	Long Ton (2240 LB)	Weight
TOZ	Ounces, Troy or Apoth	Weight

Note 4

Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

Product: 1000 cases of mineral water, 24/12 ounce bottles in each case

Units 1-Quantity	1000
Units 1-Measure	CS
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	12

Units 3-Measure	FOZ (Last level of packaging must be a base unit.)

Record Identifier PG27 (Container Information)

This is an optional PGA input record that provides data pertaining to the shipping Container Number. The Number of the shipping container is included in the Bill of Lading. Hence this record is not needed. This record may be repeated.

Record Identifier PG26 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“27”	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill of Lading.	
Container Number (Equipment ID)	20AN	28-47	O	The number of the shipping container as entered in the Bill of Lading.	
Container Number (Equipment ID)	20AN	51-70	O	The number of the shipping container as entered in the Bill of Lading.	
Filler	7X	74-80	O	Space fill	

Record Identifier PG28 (Can Dimensions – Acidified and LACF only)

For Acidified (AF) and Low Acid Canned Food (LACF) this is a conditional PGA input record that provides data pertaining to reporting Container Dimensions for the Food and Drug.

Record Identifier PG28 (Can Dimensions – LACF only)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"28"	
Can Dimensions #1	4N	5-8	C	The first dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the container is cylindrical, the dimensions are in diameter and height order. Container dimension information is restricted to use with acidified and low acid canned foods. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Can Dimensions #2	4N	9-12	C	The second dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the container is cylindrical, the dimensions are in diameter and height order. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Can Dimension #3	4N	13-16	C	The third dimension. If the container is rectangle, the dimension is in width, height, and length order. The first two spaces are inches. The second two positions are in 16ths.	1, 2

Note 1:

IF Government Agency Program Code = FOO and
If the product is Low-Acid Canned Food (LACF) or Acidified Food (AF), <u>one of the following</u> must be provided:

1. Container Measurements in PG28 (either height and diameter or height/length, width and thickness **OR**
2. Container Volume (VOL) in PG23

Note 2:

If the container is <u>rectangular</u>, the dimensions are in width, height & length order. Each dimension is expressed as a four-digit number. The first 2 digits give the number of whole inches. The next two digits give the additional fraction of the dimension expressed as sixteenths of an inch.

E.g. 1404 x 0800 x 0608 represents 14 4/16" width, 8" height and 6 8/16" length.

If the container is <u>cylindrical</u> the dimensions are in diameter & height order. Each dimension is expressed as a three-digit number. The first digit gives the number of whole inches. The next two digits give the additional fraction of the dimension expressed as sixteenths of an inch.

E.g. 300 x 108 represents 3" diameter & 1 8/16" height.

Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products and the Foreign Trade Zone facility that the goods are being withdrawn from, if applicable.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date, time and location of arrival is Mandatory..

For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required to exempt the shipment from prior notice because the requirements were previously met entering the Foreign Trade Zone.

Record Identifier PG30 (Port of Arrival / Entry Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“30”	
Status	1A	5	M	A = Anticipated arrival information If entry type = 21, then repeat PG30 and enter F = Foreign Trade Zone.	1
Anticipated Arrival/ Entry date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format. Not Mandatory for Status = ’F’.	1
Anticipated Arrival / Entry time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid). Not Mandatory for Status = ‘F’.	1
Anticipated Arrival / Entry Location Code (or Foreign Trade Zone Firm Code if repeating the record for entry type 21)	4AN	18-21	C	Either a value of ‘2’ (= Census Schedule D representing the CBP port codes) OR 4 (=FIRMS Codes) is allowed.	
Anticipated Port of Arrival / Entry	50X	22-71	O	For valid port codes, Refer to Note 1. For valid Firms Codes, Refer to ACS/ACE query.	2
Filler	8X	72-80	M	Space fill	

Note 1:

For Non-PN shipments, A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms “port” and “port of entry” refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms “port” and “port of entry” incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not “ports of entry” within the meaning of these regulations).

Note 2:

Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“55”	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fills.	

Record Identifier PG60 (Additional Information)

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”60”	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	72X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Note 1

Valid Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	**Description**
ENA	Entity Name for PG19
AD1	Entity address Line 1 for PG19
AD2	Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Entity City for PG20
INA	Individual Name for PG21
EMA	Email Address for PG21
TBN	Trade/Brand Name for PG07

PG60 record should follow immediately after its parent. For example, a PG60:ENA record should follow PG19 and a PG60:TBN record should follow PG07.

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping

In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Medical Devices Commodity Data Elements and Values

Medical Device commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Medical Devices	DEV	Radiation Emitting Devices *	RED
FDA	Medical Devices	DEV	Non-Radiation Emitting Devices	NED

Table 5 – Medical Devices commodity hierarchy

* If Radiation Emitting Devices then all Medical Device data is required in addition to all applicable PG23 data elements for radiation-emitting products. See also PG23 for Radiation Emitting Products.

In submitting a Medical Device PGA Message Set to FDA, Importers are identifying themselves, the commodity, the intended use, the quantity of the commodity and valid FDA Affirmation of Compliance code values.

The following are the potential PGA records associated with submitting Medical Devices:

PG Record	Description
OI	The commercial description of the shipment
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	Product Identifier; the item type and Product Code detail are provided.
PG06	Source Type(origin) other than the CBP country of origin is provided
PG07	The Trade/Brand Name, Model and Year of Manufacture are provided
PG10	Product Characteristics and other optional product information are provided
PG19	Entity Role (manufacturer, FDA importer, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1 are provided.
PG20	Additional address data on the entity in PG19 is provided
PG21	Individual Name, Telephone Number, and Email address are provided
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Data pertaining to issued Container Number is provided

PG Record	Description
PG30	Data pertaining to date, time and location of inspection are provided
PG55	Identifies Entity from the previous PG19, PG20 and PG21 group as having additional roles.
PG60	Additional Information
PG00	Data substitution

Medical Devices Example

A shipment of Pediatric Tourniquet Cuff Set, is imported into the United States for domestic consumption.

Medical Device Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.5 Example PG Message Sets.xlsx Tab: *Medical Devices***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message Set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“OI”	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, PEDIATRIC TOURNIQUET CUFF SET.	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"DEV"	1, 2
Government Agency Processing Code	3AN	14-16	C	Allowed values are 'RED' and 'NED'	1, 2
Intended Use Code	16X	42-57	C	Code identifying the intended use for the commodity after importation. For example, 081.001 (For Human Medical Use as a Medical Device).	3
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	

Refer to Table 5 above for commodity type and sub-type for Medical Devices

Note 1
See Table 5 above for the commodity hierarchy for Medical Devices commodities.

Note 2
If the product is to be disclaimed, then these data elements should both be populated with 'FDA'. Otherwise, the Government Agency Program Code, Government Agency Processing Code and Intended Use Code are mandatory.

Note 3
Intended Use Codes and their descriptions can be found in Appendix R (Intended Use Codes for ACE) of the ACE ABI CATAIR publication. For Medical Devices, only one of the following Intended Use Codes may beentered:

Intended Use Code	**Intended Use Definition**	**Relevant Medical Device Import Scenarios**
081.001	For Human Medical Use as a Medical Device	• Standard import of a medical device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device
081.002	For Human Medical Use as a Medical Device for Domestic	

Intended Use Code	Intended Use Definition	Relevant Medical Device Import Scenarios
	Refurbishing	
081.003	For Human Medical Use as Medical Device–domestically manufactured device that is part of a medical device convenience kit	
081.004	For Human Medical Use as a Medical Device –foreign manufactured device that is part of a medical device convenience kit	
081.005	Importation of a device constituent part (finished device) for use in a medical product regulated under a drug (CDER) application type (e.g., for use in an NDA/ANDA/BLA drug-device combination product).	
081.006	Import of a medical device under enforcement discretion provisions per final guidance: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm401996.pdf	Applicable product codes for CBP business rule: 80O - - UG; 86N - - FF 86N - - FG; 80N - - XQ 90L - - MB; 90L - - MD
100.000	For Personal Use as a Non-Food Product – for personal use as a medical device	
110.000	For Public Exhibition or Display as a Non-Food Product	• Includes import of device for trade show
140.000	For Charitable Organization Use as a Non-Food Product	
081.007	Component for further manufacturing into a finished medical device	
081.008	Importation of a device component for use in a medical product regulated under a drug (CDER) application type (e.g., for use in an NDA/ANDA/BLA drug-device combination product).	
170.000	For Repair of a Non-Food Product	• Repair of medical device and re-exportation
180.010	For Research and Development as a Non-Food Product - For research and development as a medical device	• Import of research or investigational use in vitro diagnostic device
180.014	For Research and Development as a Non-Food Product – for bench testing or nonclinical research use	• Import of a device for non-clinical use/bench testing • Import of device sample for customer evaluation
180.015	For Research and Development as a Non-Food Product – import of a medical device for clinical investigational use	
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	• Refund/overstock • Bench Testing • Corrective Action Prevention Action (CAPA) Plan Investigation • Recall
920.002	Import of a device that is US goods returned for sale to a third party	
940.000	Import of a Compassionate Use/Emergency Use Device	
950.001	Import of a single-use device for domestic reprocessing	
950.002	Import of a multi-use device for domestic reprocessing	
970.000	Import for Export	• Import of a medical device for further processing and re-exportation • Import of medical device or accessory for further manufacturing into an export only medical device
970.001	Import for Export	• Import of a medical device component for further manufacturing into an export only medical device
UNK	Unknown	• UNK is allowed when the filer does not know the applicable IUC code. However, the value UNK is treated as if 081.001 was entered when validating the AoC codes in PG23

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate if the following records relate to a product (P) by specifying the Item Type.

For Medical Device entries, the Product Code Number is provided within this record.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	"FDP".	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Note 1
Product Code Qualifiers and their descriptions can be found in CBP's Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Medical Devices, this is currently always 'FDP' for all FDA products.

Only one Product Code Number per line is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

IF Government Agency Program Code = 'DEV'
THEN PRODUCT.CODE.INDUSTRY is BETWEEN 73 and 92 (inclusive)

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"06".	
Source Type Code	3AN	5-7	M	Mandatory valid values are 30 (Country of Source) for a component or 39 (Country of Production) for a finished product. 294 (Country of Refusal) is MANDATORY if previously refused. There would be one PG06 with source type code of either 30 or 39. If previously refused, then trade would also provide another PG06 with source type code 294.	1
Country Code	2X	8-9	M	Country of production or source is required for Medical Devices.	2

Note 1
Source Type Codes and their descriptions can be found in CBP's Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2
Any of the country codes from CBP's Appendix B (ISO Country and Currency Codes) in the ACE ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

For Medical Device, this is a conditional PGA input record that provides FDA with data pertaining to the Trade Name.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name	35X	5-39	O	Trade/Brand Name of the Medical Device. For example, "Zimmer Reusable Tourniquet Cuff". Please see Note 1 below. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code 'TBN'.	1

Note 1

DEV/NED: The Trade Name is optional. Encouraged, if provided on the invoice or otherwise available to the filer.
DEV/RED: The trade Name is conditional. See radiation-emitting products chapter

Record Identifier PG10 (Product Characteristics)

This is a mandatory PGA input record that allows for reporting codes that provide additional characteristics of a product , not reported elsewhere in the PG Message Set. For example, this record can be used to provide the model year of a product, which can be different from the year of manufacture provided in the PG07.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	”10”	
Commodity Characteristic Description	57X	24-80	M	Free form description, NOT product code description, of the item, to supplement the above data elements. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Medical Devices, this is a mandatory PGA input record requiring Entity Role Code, Entity Name, and Entity Address 1.

Entity Identification Code and Entity number are optional data elements, but they are listed as conditional because If opting to transmit Entity Identification Code then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2. Conditional, based on the roles and if they have been supplied at the entry and line	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code 'ENA'. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code 'AD1'. See validation criteria below.	2

Note 1
Entity Role Codes and their descriptions can be found in CBP's Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Device Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer 1 (Importer of Record)
	DII	Device Initial Importer*
	DP	Delivered To Party

§ Same Role Code cannot be entered more than once.
* If there's no DII that must register, the name and address of the US based firm receiving the goods is required. Reference: 21 CFR 807.3 (g): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=807.3

List of Entity Role codes optional to FDA Medical Device Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Note 2
Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Medical Device Message Sets is below:

Data Element	*Code*	*Description*	*Length/ Class*
Entity Identification Codes	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA/CDRH prefers to use FEI numbers for identifying the device Entities; IF FEI is not available THEN provide DUNS.

For devices the vast majority of registration numbers are FEIs

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N
ELSE IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity..

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code ‘AD2’.	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	
Entity City	21X	42-62	M	For example, SAN DIEGO. If Entity City requires additional space, continue in a PG60 record with Qualifier Code ‘ECI’.	
Entity State/Province	3AN	63-65	C	For example, CA.	2
Entity Country	2A	66-67	M	For example, US.	
Entity Zip/Postal Code	9X	68-76	C	For example, 92169.	2
Filler	4X	77-80	M	Space fill	

Note 1: If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes ‘AD3’, ‘AD4’ and ‘AD5’ immediately under the PG20 record for the same Entity.

Note 2: Required if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides point of contact information.

For each FDA entry line, at least one PG21 is required with the individual qualifier “FD1” (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier “PK” which should be the point of contact for the filer/broker. “PK” may be sent in one of the following ways:

- under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer) *FDA preferred method
- or as a secondary PG21 to FD1 using individual qualifier “PK” (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), or
- under any other required PG19 entity as long as “PK” is the individual qualifier in PG21.

If provided, there should be only one PK per entry line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“21”	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only “FD1” and “PK” are allowed.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code ‘INA’.	
Telephone Number of the Individual	15X	31-45	M	For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address needs more space, continue in a PG60 record with Qualifier Code ‘EMA’.	

Record Identifier PG23 (Affirmation of Compliance)

For Medical Device, this is a conditional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements.	1
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. This could include a combination of letters and digits, specific text, etc. Follow the *Entered value of AoC Description / Business Rule* column in the table below in the Note section.	1
Filler	1X	80	M	Space fill	

Note 1
The list of Affirmation of Compliance codes for FDA-Medical Devices Message Sets is below, followed by the import scenarios/Intended Use Codes indicating when the AofCs should be provided N=Numeric digits; X=Alphanumeric.

Code	***Description***	***Syntax***
PM#	Device Premarket Number	Any of the following: P+6N; N+4N, 5N, or 6N; D+6N; H+6N; K+6N; DEN+6N; BP + 4-6N; BK + 6N; BH + 6N; BM + 6N; BR + 6N; DK + 6N; BD+6N
DDM	Device Domestic Manufacturer	1 - 10N
DEV	Device Foreign Manufacturer Registration Number	1 - 10N
DFE	Device Foreign Exporter Registration Number	1 - 10N
DI	Device Identifier	6-23X
CPT	Component Identifier	Indicator only
IFE	Import For Export	Indicator only
ERR	Entry Review Requested	Indicator only
IDE	Investigational Device Exemption Number	Any of the following: 4N; 5N; G+6N; OR "NSR"; when using G+6N, 'G000000' is not allowed; 0000 and 00000 are not allowed;
IRC	Device Impact Resistance Lens Certification	Indicator only
KIT	Device Imported Kit of Finished Device	Indicator only
LST	Device Listing Number	A+6N; B+6N; C+6N; D+6N; E+6N; L+6N; Q+6N; R+6N
DA	New Drug Application Number or Abbreviated New Drug Application Number or Therapeutic Biologic Application Number	BA+4-6N or BN + 5-6 N or 6N
IND	Investigation New Drug Application Number	4-6N
LWC	Electrode Lead Wire Or Patient Cable	Indicator Only

The table below shows which Affirmations of Compliance are Mandatory (M), Conditional (C) or Optional (O) based on the Intended Use Code/Import Scenario:

Intended Use (see PG01 for definitions)	Import Scenarios	Mandatory Affirmations	Conditional[1] Affirmations	Optional Affirmations
081.001 or UNK	• Standard import of device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device	DEV, DFE, LST	IRC, LWC, PM#	DI
081.002*	Import of a device for domestic refurbishing	DEV, DFE, LST	IRC, LWC, PM#	DI
081.003	domestically manufactured device that is part of a medical device convenience kit	DDM, DFE, KIT, LST	IRC, LWC, PM#	DI
081.004	foreign manufactured device that is Part of a medical device convenience kit	KIT, DEV, DFE, LST	PM#, LWC;IRC	DI
081.005	Device constituent part for drug-device combination product	DEV, DFE, LST	DA, IND	
140.000	Import of a device for charity	DEV, DFE, LST	IRC, LWC, PM#	DI
081.007	Component for further manufacturing into a finished medical device	CPT		LST, PM#
081.008	Device component for use in a drug-device combination product	CPT	DA, IND	
170.000	Repair of medical device and re-exportation	IFE	DFE, LST, IRC, LWC, PM#, DDM	DI
180.010	Import of research or investigational use in vitro diagnostic device			
180.014*	• Import of a device for non-clinical use/bench testing • Import of device sample for customer evaluation			
180.015*	Import of a medical device for clinical investigational use	IDE		
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	DDM, LST	DFE, IRC, LWC, PM#	DI
920.002	Import of device that is US goods returned for sale to a third party	DFE, DDM, LST	IRC, LWC, PM#	DI
950.001*	Import of a single-use device for domestic reprocessing	DDM, LST	DFE, IRC, LWC, PM#	DI
950.002*	Import of a multi-use device for domestic reprocessing		DDM, DFE, IRC, LST, LWC, PM#	DI
970.000	Import for Export: • Import of a medical device for further processing and re-exportation • Importation of a medical device or accessory for further manufacturing into an export-only medical device	DEV, DFE, IFE, LST		
970.001	Import for Export: • Importation of a medical device component for further manufacturing into an export-only medical device	IFE, CPT, DDM, LST		
100.000*	• Device For Personal Use			
110.000*	• Public Exhibition/Trade Show			
940.000*	• Compassionate Use/Emergency device			

Intended Use (see PG01 for definitions)	Import Scenarios	Mandatory Affirmations	Conditional[1] Affirmations	Optional Affirmations
081.006	• Import under enforcement discretion provisions per final guidance			

[1]: The conditional affirmations are required if applicable to the product being declared.
For example, if the product requires premarket clearance (510(k)), then PM# must be provided.

*Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

The list of Optional Affirmation of Compliance codes for FDA-Medical Devices Message Sets is below.

Code	***Description***	***Syntax***
DI	Device Identifier (part of the Unique Device Identifier, UDI)	6-23X
ERR	Entry Review Requested	Indicator only

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be GEN.

If GEN, the PG24 is applicable to the preceding PG02. Only one PG24:GEN is allowed per PG02 (this is to avoid multiple PG24:GEN records without a guaranteed sequencing as intended by the filer).

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”24”	
Remarks Type Code	3X	5-7	O	FDA uses only GEN as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Record Identifier PG25 (Product Condition)

For Medical Devices, this is an optional PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers. If transmitted, the line value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X". This is left blank for a positive value.	
Actual Temperature	6N	8-13	O	Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier	1AN	15	O	Code of the entity that assigned the Lot number. 1 = Manufacturer Should not be entered if more than one PG25 record is entered	
Lot Number	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays while the missing information is obtained. If entered: The value associated with the PGA line number is in whole dollars. Should be entered only in the first PG25 record in the case of multiple PG25 records. If entered, must be right-justified	

				with preceding zeros and be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

Record Identifier PG26 (Product Packaging)

For Medical Devices, this is a conditional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. Quantity is optional for processing code “NED” and mandatory for processing code “RED” if the product requires a 2877. If opting to transmit quantity, Packaging Qualifier, Quantity, and Unit of Measure must all be provided. Quantity should be transmitted in accordance with the following instructions:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any ‘Packaging Qualifier’ number level requires all levels under it to be represented. For instance, level 3 can’t be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“26”	
Packaging Qualifier	1N	5	C	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	C	Although quantity is optional for DEV/NED, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays while the missing information is obtained. Quantity is conditional for DEV/RED. See the Radiation Emitting Products chapter (PG26) for further discussions on this topic. When entered: This is the Quantity of the packaging level, For example, 000000000400. Two decimal places are implied. Must be greater than zero. Entering Quantity shall require entering Packaging Qualifier and the Unit of Measure.	2,4
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. At least, ‘Pieces’ must be selected. Cannot be repeated among the PG26 records.	3,4

Note 1

This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Medical Devices Message Sets:
Valid FDA Units of Measure for Packaging Containers

Code	***Description***
CS	Case
CT	Carton
BX	Box
PK	Package

Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	***Description***
PCS	Pieces (Count)

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 200 cartons, 6 boxes, 8 pieces, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

200 Cartons of 6 boxes of PEDIATRIC TOURNIQUET CUFF SET in each carton
8 pieces per box

Units 1-Quantity	200
Units 1-Measure	CT
Units 2-Quantity	6
Units 2-Measure	BX
Units 3-Quantity	8
Units 3-Measure	PCS

For Medical Devices, the lowest unit of measure must be PCS (Pieces – Count).

Record Identifier PG27 (Container Information)

This is an optional PGA input record that provides data pertaining to the shipping Container Number. The Number of the shipping container is included in the Bill of Lading. Hence this record is not needed. This record may be repeated.

Record Identifier PG26 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"27"	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill of Lading.	
Container Number (Equipment ID)	20AN	28-47	O	The number of the shipping container as entered in the Bill of Lading.	
Container Number (Equipment ID)	20AN	51-70	O	The number of the shipping container as entered in the Bill of Lading.	

Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival/Entry Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is Mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Port of Arrival / Entry Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Inspection/ Laboratory Testing Status	1A	5	M	A = Anticipated arrival information. If entry type = 21, then repeat PG30 and enter F = Foreign Trade Zone.	1
Anticipated Arrival / Entry date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	1
Anticipated Arrival / Entry time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	1
Anticipated Arrival / Entry Location Code	4AN	18-21	O	Only a value of '2' (= Census Schedule D representing the CBP port codes) OR 4 (=FIRMS Code) is allowed.	
Anticipated Port of Arrival / Entry	50X	22-71	O	For valid port codes, refer to Note 1.	2
Filler	8X	72-80	M	Space fill	

Note 1:

For Non-PN shipments, A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms “port” and “port of entry” refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms “port” and “port of entry” incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not “ports of entry” within the meaning of these regulations).
Note 2:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“55”	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Record Identifier PG60 (Additional Information)

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”60”	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	72X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Note 1

Valid Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	**Description**
ENA	Entity Name for PG19
AD1	Entity address Line 1 for PG19
AD2	Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Entity City for PG20
INA	Individual Name for PG21
EMA	Email Address for PG21
TBN	Trade/Brand Name for PG07

PG60 record should follow immediately after its parent. For example, a PG60:ENA record should follow PG19 and a PG60:TBN record should follow PG07.

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping

In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Tobacco Commodity Data Elements and Values

Tobacco commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code±
FDA	Tobacco	TOB	Consumer Use	CSU
FDA	Tobacco	TOB	For Further Manufacturing	FFM
FDA	Tobacco	TOB	Investigational	INV

Table 6 – Tobacco commodity hierarchy

± Required to identify a tobacco product as "for further manufacturing (FFM)", for "consumer use" (CSU), or for "investigational use" (INV). This information is needed to determine the marketing status of the product. Ref: Sections 905, 910, and 911 of the FD&C Act.

The following are the potential PGA records associated with submitting Tobacco Products:

PG Record	Description
OI	The commercial description of the shipment is provided.
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	The item type and Product Code detail are provided.
PG06	Source Type(origin) other than the CBP country of origin is provided
PG07	The Trade/Brand Name, Model and Year of Manufacture are provided
PG10	Product Characteristics and other optional product information are provided
PG19	The entity (manufacturer, consignee, shipper, etc.) of Record's identification information is provided.
PG20	Additional address data on the entity in PG19 is provided
PG21	The entity (manufacturer, consignee, shipper, etc.) of Record's individual point of contact, phone number and email is given.
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG30	Inspection/Laboratory Testing
PG55	Additional roles performed by entity or individual

PG Record	Description
PG60	Additional Information
PG00	Data Substitution

Tobacco Example

Tobacco Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.5 Example PG Message Sets.xlsx Tab: *Tobacco***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message Set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"OI"	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, Tobacco leaves - unprocessed	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"TOB"	1, 2
Government Agency Processing Code	3AN	14-16	C	Allowed values: CSU, FFM, INV	1, 2
Intended Use Code	16X	42-57	C	The Government Agency Processing Code and the Product Code should provide all the information the FDA need to know about the intended use.	3,4
Intended Use Description	21X	58-78	O	N/A for FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	3

Note 1

See Table 6 above for the commodity hierarchy for Tobacco commodities.

Note 2

If the product is Disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code, Government Agency Processing Code are mandatory.

Note 3

If the Disclaimer is 'A' then these data elements are optional; otherwise the Intended Use Code is conditional. If Government Agency Program Code = TOB and Government Agency Processing Code = INV then one of the 180 Base Code Intended Use Codes must be supplied.

Note 4

Intended Use Code	Intended Use Description
150.000	for commercial process as non-food

155.000	For Commercial Assembly as a Non-Food Product to be consumed
180.001	For Research and Development as a non-Food Product - Animal or plant for biomedical research
180.000	For Research and Development as a non-Food Product – All other Uses
110.000	For Public Exhibition or Display as a Non-Food Product
130.000	For Consumer Use as a Non- Food Product
140.000	For Charitable Organization Use as Non-Food Product
130.037	For re-packaging and re-labelling**

**** Although Section 905 of the FD&C Act only applies to domestic manufacturers, it's important for enforcement purposes to know when products are being imported for repackaging or relabeling because the re-packagers / re-labelers will need to register with FDA. Under Section 905, the term "manufacture, preparation, compounding, or processing" includes repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. Ref: 701(b); Section 905 of the FD&C Act (21 U.S.C. §387e)

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Note 1

Product Code Qualifiers and their descriptions can be found in CBP's Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Tobacco, this is currently always 'FDP' for all FDA products.

Only one FDA Product Code Number per line is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

IF Government Agency Program Code = 'TOB'
THEN PRODUCT.CODE.INDUSTRY = 98

Record Identifier PG06 (Product Origin)

This is a conditional PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin, .

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	C	For Tobacco, Source Type Code 39 (Country of Production) is required. Other Source Type Codes, 262 (Place of Growth) or HRV (Harvested) or 30 (Country of Source) may be entered, if available. There would be at least one PG06 with source type code of 39. More PG06 records may be repeated for the optional Source Type Codes, 262, HRV or 30.. Additionally, if previously refused, then trade would also provide another PG06 with source type code 294 (Country of Refusal).	1
Country Code	2X	8-9	C	Country of production or source is required for Tobacco.	2

Note 1

Source Type Codes and their descriptions can be found in CBP's Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from CBP's Appendix B (ISO Country and Currency Codes) in the ACE ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is a conditional PGA input record that provides data pertaining to Trade or Brand Name.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name**	35X	5-39	C	If Government Agency Processing Code is CSU (Consumer Use) then trade or brand name is mandatory. If Government Agency Processing Code is FFM (For Further Manufacturing) or INV (Investigational), then trade name/brand name is optional. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code 'TBN'.	

** This field is only required for products intended for consumer use, not for products intended for further manufacturing and for investigational use. Brand name is required in order to help identify if the product meets FDA's pre-market authorization requirements under Section 910 of the FD&C Act.

Record Identifier PG10 (Product Characteristics)

For Tobacco, this is a mandatory PGA input record that allows for importer to report the description of the product at the line level to capture the information currently collected in multiple OI records. .

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“10”	
Commodity Characteristic Description	57X	24-80	M	Free form invoice description, NOT product code description. This field will capture such information as length, color, and pack count. Under 21 1140.16(b), cigarette packages are required to contain a minimum of 20 cigarettes. See Appendix A for the use of PG10 to capture the information such as length, color and pack count.	

Record Identifier PG19 (Entity Data)

For Tobacco, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role, Entity Name and Entity Address 1. Entity Identification is a conditional data element.

Record Identifier PG19 (Entity Data)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example: MF, DP	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example: 16 (DUNS #), 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	Mandatory, if Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code 'ENA'. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code 'AD1'. See validation criteria below.	2

Note 1

Entity Role Codes and their descriptions can be found in CBP's Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Tobacco Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered to Party

§ Same Role Code cannot be entered more than once.

List of Entity Role codes **conditional** to FDA Tobacco Message Sets is below:

(If Government Agency Processing Code is INV then either ITL or LAB is mandatory.

Data Element	***Code***	***Description***
Entity Identification Codes	ITL	Independent Third Party Laboratory
	LAB	Laboratory or Clinical Site

List of Entity Role codes also applicable to FDA Tobacco Message Sets is below:

Data Element	Code	Description
Entity Role Codes	RD	Retailer/Distributor
	TB	Submitter

List of Entity Role codes optional to FDA Tobacco Message Sets:

Data Element	Code	Description
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Tobacco Message Sets is below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA/CTP requires Entity Name and Entity Address. Additionally, an FEI number is preferred to import in to the U.S.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

ELSE Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N

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Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity..

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code ‘AD2’.	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	
Entity City	21X	42-62	M	For example, SUGARLAND. If Entity City requires additional space, continue in a PG60 record with Qualifier Code ‘ECI’.	
Entity State/Province	3AN	63-65	C	For example, TX.	2
Entity Country	2A	66-67	M	For example, US.	
Entity Zip/Postal Code	9X	68-76	C	For example, 77004.	2
Filler	4X	77-80	C	Space fill	

Note 1: If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes ‘AD3’, ‘AD4’ and ‘AD5’ immediately under the PG20 record for the same Entity.

Note 2: Required if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides FDA with data about an Individual Point of Contact (POC) related to the Entity (the party) in the preceding PG19 record. Included in this record are the Individual Name, Telephone Number and Email address. A typical example is a POC for the Filer.

For each FDA entry line, at least one PG21 is required with the individual qualifier “FD1” (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier “PK” which should be the point of contact for the filer/broker. “PK” may be sent in one of the following ways:

- under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer) *FDA preferred method
- or as a secondary PG21 to FD1 using individual qualifier “PK” (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), or
- under any other required PG19 entity as long as “PK” is the individual qualifier in PG21.

If provided, there should be only one PK per entry line.

Although the PK (filer contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record to obtain the contact information for the filer. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“21”	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only FD1 and PK are allowed.	1
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code ‘INA’.	
Telephone Number of the Individual	15X	31-45	M	For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address needs more space, continue in a PG60 record with Qualifier Code ‘EMA’.	

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication.

Record Identifier PG23 (Affirmation of Compliance)

For Tobacco, this is an optional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	O	A code used to affirm compliance with FDA requirements. See table below for valid affirmation codes.	1
Affirmation of Compliance Qualifier	30X	10-39	O	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see CBP's Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) for valid codes related to certain specific Affirmation of Compliance codes.	
Filler	1X	80	M	Space fill	

Note 1
The FDA Affirmation of Compliance Codes and their descriptions are listed in the Appendix PGA (Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes) of ACE ABI CATAIR publication. The list of AoC codes **optional** to FDA Tobacco Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	ILS	Confirmation of **Ingredient Listings Submission** to FDA: Manufacturers and importers of tobacco products to the U.S. must provide a list of ingredients to FDA. Code of "ILS" affirms Ingredients Listings was previously submitted.	Indicator only	If Government Agency Processing Code is "CSU", then "ILS" may be entered.
	HPC	**Harmful or Potentially Harmful Constituents (HPHC)** Report: All manufacturers and importers of tobacco products to the U.S. must provide HPHC information to FDA. Code of "HPC" confirms HPHC information was previously submitted.	Indicator only	If Government Agency Processing Code is "CSU", then "HPC" may be entered.
	CMT	**Commercially Marketed Tobacco.** Code of "CMT" **indicates that the product was** commercially marketed in the U.S. as of February 15, 2007	Indicator only	If Government Agency Processing Code is "CSU" and the product was commercially marketed in the U.S. as of February 15, 2007, then "CMT" may be entered.

Data Element	Code	Description	Syntax	Business Rules
	SE or PMT or EXE	If the product was not commercially marketed in the U.S. as of February 15, 2007, then SE = Substantially Equivalent or PMT= Premarket Tobacco Application, or EXE= Exemption from Substantial Equivalence may be affirmed.	Indicator only	If Government Agency Processing Code is “CSU” and the product was not commercially marketed in the U.S. as of February 15, 2007 (CMT was not declared), then either SE, PMT, or EXE may be entered.
	TST	Tobacco Submission Tracking	7X or 7X-24X	If Government Agency Processing Code is “CSU” and affirmations “SE”, “PMT”, or “EXE” were declared, then “TST” is entered. (i.e. “TST may be entered if product was not commercially marketed in the U.S. as of February 15, 2007) If declaring CMT, then TST is optional.
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be GEN.

If GEN, the PG24 is applicable to the preceding PG02. Only one PG24:GEN is allowed per PG02 (this is to avoid multiple PG24:GEN records without a guaranteed sequencing as intended by the filer).

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”24”	
Remarks Type Code	3X	5-7	O	FDA uses only GEN as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Record Identifier PG25 (Product Condition)

This is an optional PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers and the line value may be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier**	1AN	15	O	Includes Lots and/or Batches IF Government Agency Program Code = TOB THEN Lot Number Qualifier = 3 Should not be entered if more than one PG25 record is entered	
Lot Number**	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
Production Start date of the Lot**	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot**	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays while the missing information is obtained. If entered: The value associated with the PGA line number is in whole dollars and should be entered only in the first PG25 record in the case of multiple PG25 records. If entered, must be right-justified with	

				preceding zeros and be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

** Not currently required for importing tobacco products, but may be required in future CTP regulations. Ref: 21 CFR 7; 701(b)

Record Identifier PG26 (Product Packaging)

For Tobacco, this is an optional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. If included, please adhere to the following rules:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container and be a code from the table of base units listed below.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present. The same unit of measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	O	Used to determine the quantity of tobacco products being imported, such as the number of cigarettes, cartons, cartons per pack, etc. Under 21 1140.16(b), cigarette packages are required to contain a minimum of 20 cigarettes. This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	O	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays while the missing information is obtained. If entered, this is the total quantity for the packaging level. Must be greater than zero. Two decimal places are implied. The base quantity must always be the last quantity transmitted. Entering Quantity shall require entering Packaging Qualifier and the Unit of Measure.	2, 4

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Unit of Measure (Packaging Level)	5X	18-22	O	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3, 4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Tobacco Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix D in this document or to the Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Valid FDA Units of Measure for Packaging Containers

Code	*Description*
CS	Case
CT	Carton
BX	Box
PK	Package

Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	*Description*
DOZ	Dozen (Count)
DPC	Dozen Pieces (Count)
NO	Number (Count)
PCS	Pieces (Count)

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

For example:
Product: 1000 cartons of cigarettes, 10 packs in each carton, 20 cigarettes in each pack

Units 1-Quantity= 1000
Units 1-Measure =CT
Units 2-Quantity=10
Units 2-Measure=PK
Units 3-Quantity=20

Units 3-Measure=PCS

Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival/Entry Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is Mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Port of Arrival / Entry Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Inspection/ Laboratory Testing Status	1A	5	M	A = Anticipated arrival information. If entry type = 21, then repeat PG30 and enter F = Foreign Trade Zone.	1
Anticipated Arrival / Entry date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	1
Anticipated Arrival/ Entry time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	1
Anticipated Arrival / Entry Location Code	4AN	18-21	O	Only a value of '2' (= Census Schedule D representing the CBP port codes) OR 4 (=FIRMS Code) is allowed.	
Anticipated Port of Arrival / Entry	50X	22-71	O	For valid port codes, refer to Note 1.	2
Filler	8X	72-80	M	Space fill	

Note 1:

For Non-PN shipments, A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2:

Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“55”	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fills.	

Record Identifier PG60 (Additional Information)

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”60”	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	72X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Note 1

Valid Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	**Description**
ENA	Entity Name for PG19
AD1	Entity address Line 1 for PG19
AD2	Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Entity City for PG20
INA	Individual Name for PG21
EMA	Email Address for PG21
TBN	Trade/Brand Name for PG07

PG60 record should follow immediately after its parent. For example, a PG60:ENA record should follow PG19 and a PG60:TBN record should follow PG07.

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping

In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Radiation Emitting Products Commodity Data Elements and Values

Radiation Emitting Product commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message.

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Radiation Emitting Products	RAD	Non-Medical Radiation Emitting Products	REP

Table 7 – Radiation Emitting Products commodity hierarchy

For informational purposes, the following table describes the Radiation Emitting Categories and whether the product requires a 2877 and whether the product is a medical device. The Radiation Emitting Product Classification website provides information on radiation emitting products. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm

Radiation Emitting Product Category	2877 Required	Medical Device*
Diagnostic Ultrasound Devices	N	Y
Sonic Medical Products	N	Y
Sonic Non-Medical Products	N	N
Therapeutic Ultrasonic Devices (Certified)	Y	Y
Ultrasonic Medical Devices (Miscellaneous)	N	Y
Ultrasound Non-Medical Devices	N	N
Veterinary Diagnostic Ultrasonic Products	N	N
Veterinary Therapy Ultrasonic Products	Y	N
Analytical X-Ray Systems, Non-Medical	N	N
Cabinet X-Ray Systems, Medical	Y	Y
Cabinet X-Ray Systems, Non-Medical	Y	N
Cargo Non-Intrusive Security Systems	N	N
Cathode Ray Tube (without Electronics Chassis)	N	N
Cold-Cathode Gas Discharge Tubes	Y	N
Dental Diagnostic X-Ray Equipment	Y	Y
Diagnostic Nuclear Medicine Devices	N	Y
Diagnostic X-Ray Equipment (Non-Certified)	N	N

Radiation Emitting Product Category	2877 Required	Medical Device*
High Voltage Vacuum Switches	N	N
High Voltage Vacuum Tubes	N	N
Industrial Particle Beam Systems	N	N
Industrial X-Ray Systems (Excluding Cabinet)	N	N
Medical Accelerators	N	Y
Medical Diagnostic X-Ray Equipment	Y	Y, except product codes RCA, RCB, RBZ, RCD
Non-Medical Accelerators	N	N
Personnel Security Systems	N	N
Radioisotope Therapy Devices	N	Y
Therapeutic X-Ray Systems	N	Y
TV Receivers & Products Containing Same	Y	ONLY the following product codes are medical devices: FET, FWB, FWC, FWD, FWE, FWF, FWG, HJG, and ODA. All other product codes in this category are not medical devices.
Veterinary X-Ray Systems	N	N
X-Ray Bone Densitometers	N	Y
X-Ray Film and Film Processing Materials	N	ONLY the following product codes are medical devices: LQA and JAC. All other product codes in this category are not medical devices.
Household ELF Products	N	N
Industrial Dielectric Heaters	N	N
Microwave Communication, Data Transmit, and Measurement Products	N	N
Microwave Diathermy Machines	N	Y
Microwave Heating and Drying Products	N	N
Microwave Hyperthermia Therapy Devices	N	Y
Microwave Identification, Safety, Security, and Surveillance Products	N	N
Microwave Medical Products	N	Y, except product code RDG
Microwave Ovens (Food Prep)	Y	N
Nuclear Magnetic Resonance Devices	N	Y
Other Microwave Products	N	N

Radiation Emitting Product Category	2877 Required	Medical Device*
Data Measurement, Transmit, Control Laser Products	Y	N
General Optical Products, Medical	N	Y, except product code RGV, RGU
General Optical Products, Non-Medical	N	N
In Vitro and Other Medical Laser Products	Y	Y, except product code RGB
Laser Light Show/Display Products	Y	N
Laser Products (Pre-Standard)	N	N
Material Processing Laser Products	Y	N
Medical Laser Products	Y	Y, except product code RGC
Mercury Vapor Lamps	Y	N
Other Demonstration Laser Products	Y	N
Other Laser Products	Y	N
Positioning Medical Laser Products	Y	Y, except product code RGC
Research, Scientific, Laboratory Laser Products	Y	N
Safety, Security, Surveillance Laser Products	Y	N
Sunlamp Products (Certified)	Y	Y
Sunlamp Products (Pre-Standard)	N	N
Surveying, Leveling, Alignment Laser Products	Y	N
Toy, Novelty, Play Laser Products	Y	N
Ultraviolet Commercial/Consumer Products	N	N
Ultraviolet Hygiene Products	N	ONLY the following product codes are medical devices: LYL, MCF, NOB. All other product codes in this category are not medical devices.
Ultraviolet Medical Products	N	Y
Ultraviolet Surveillance & Detection Products	N	N
Utility/Peripheral Laser Products	Y	

Table 7a – Radiation Emitting Device Categories

***If Medical Device then all Medical Device data is required, in addition to applicable PG23 message set for radiation-emitting products. See the chapter for Medical Devices.**

The following are the potential PGA records associated with submitting Radiation-Emitting Products.

PG Record	Description
OI	The commercial description of the shipment
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	Product Identifier; the item type and Product Code detail are provided.
PG06	Source Type(origin) other than the CBP country of origin is provided
PG07	The Trade/Brand Name, Model and Year of Manufacture are provided
PG10	Product Characteristics and other optional product information are provided
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1 are provided.
PG20	Additional address data on the entity in PG19 is provided
PG21	Individual Name, Telephone Number, and Email address are provided
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Data pertaining to issued Container Number is provided
PG30	Data pertaining to date, time and location of inspection are provided
PG55	Identifies Entity from the previous PG19, PG20, and PG21 group as having additional roles.
PG60	Additional Information
PG00	Data substitution

Radiation Emitting Products Example

Radiation Emitting Products Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.5 Example PG Message Sets.xlsx Tab:** ***Radiation Emitting Products***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message Set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"OI"	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, FDR D-EVO Suite FS by Fujifilm.	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, , Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"RAD"	1, 2
Government Agency Processing Code	3AN	14-16	C	"REP"	1, 2
Intended Use Code	16X	42-57	C	Code identifying the intended use for the commodity after importation.	2,3
Intended Use Description	21X	58-78	O	If the Intended Use Code used is 980.000, this field is used to describe the Intended Use such as 'Sample devices', 'Return shipment', etc.	2,3
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	2

Note 1
See Table 7 above for the commodity hierarchy for Radiation Emitting Products commodities.

Note 2
If the product is Disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code, Government Agency Processing Code and Intended Use Code are mandatory. **Note 3**
Intended Use Codes and their descriptions can be found in Appendix R (Intended Use Codes for ACE) of the ACE ABI CATAIR publication. For Radiation-Emitting Products, only one of the following Intended Use Codes may be entered:

085.000	For Veterinary Medical Use as a Non-Food Product under Controlled Distribution
090.000	For Military Use as a Non- Food Product
100.000	For Personal Use as a Non- Food Product
110.000	For Public Exhibition or Display as a Non-Food Product
120.000	For Public Safety Use as a Non-Food Product
130.000	For Consumer Use as a Non- Food Product
140.000	For Charitable Organization Use as Non-Food Product
150.000	For Commercial Processing as a Non-Food Product
155.000	For Commercial Assembly as a Non-Food Product
170.000	For Repair of a Non-Food Product
180.000	For Research and Development as a Non-Food Product

970.000	For Import For Export
980.000	For Other Use

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P).

For Radiation-Emitting Product entries, the Product Code Number is provided within this record.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. Only one 'P' record is allowed for the same PGA Line # in PG01	
Product Code Qualifier	4AN	6-9	M	"FDP".	1
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Note 1
Product Code Qualifiers and their descriptions can be found in CBP's Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Radiation-Emitting Products, this is currently always 'FDP' for all FDA products.

Only one FDA Product Code Number per line is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

IF Government Agency Program Code = 'RAD'
THEN PRODUCT.CODE.INDUSTRY is between 94 and 97 (inclusive)

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”06”	
Source Type Code	3AN	5-7	M	Mandatory valid values are 30 (Country of Source) or 39 (Country of Production). 294 is MANDATORY (Country of Refusal) if previously refused There would be one PG06 with source type code of 30 or 39. If previously refused, then trade would also provide another PG06 with source type code 294.	1
Country Code	2X	8-9	M	A two-letter code that identifies the country from where the product was produced, packed or shipped. Valid International Organization for Standardization (ISO) Country and Currency Code codes are in Appendix B in the ACS ABI CATAIR.	2

Note 1
Source Type Codes and their descriptions can be found in CBP’s Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2
Any of the country codes from CBP’s Appendix B (ISO Country and Currency Codes) in the ACE ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is a conditional PGA input record that provides FDA with data pertaining to Name, Model, Manufacture Year, and Item Identity Number.

Record Identifier PG06 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“07”	
Trade Name/Brand Name	35X	5-39	C	Trade/Brand Name of the Radiation-Emitting Device. For example, Sony Laser scanner RM2. Please see Note 1 below. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code ‘TBN’.	1

Note 1
If product requires 2877, then brand name is mandatory.

Record Identifier PG10 (Product Characteristics)

This is a mandatory PGA input record that allows for reporting codes that provide additional characteristics of a product or component, not reported elsewhere in the PG Message Set. For example, this record can be used to provide the model year of a product, which can be different from the year of manufacture provided in the PG07.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“10”	
Commodity Characteristic Description	57X	24-80	M	Free form description (invoice description NOT product code description) of the item. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Radiation Emitting Products, this is a mandatory PGA input record requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code and Entity number are optional data elements, but they are listed as conditional because If opting to transmit Entity Identification Code then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 16 (DUNS #) or 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code 'ENA'. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code 'AD1'. See validation criteria below.	

Note 1
Entity Role Codes and their descriptions can be found in CBP's Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes applicable to FDA Radiation-Emitting Products Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party

§ Same Role Code cannot be entered more than once.

List of Entity Role codes optional to FDA Radiation Emitting Device Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact (Filer/Broker contact information)

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Medical Device Message Sets is below:

Data Element	***Code***	***Description***	***Length/ Class***
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 4 to 10 digits	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the **preceding** PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity. .

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"20"	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code 'AD2'.	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	
Entity City	21X	42-62	M	For example, SAN DIEGO. If Entity City requires additional space, continue in a PG60 record with Qualifier Code 'ECI'.	
Entity State/Province	3AN	63-65	C	For example, CA.	2
Entity Country	2A	66-67	M	For example, US.	
Entity Zip/Postal Code	9X	68-76	C	For example, 92169.	2
Filler	4X	77-80	M	Space fill	

Note 1: If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes 'AD3', 'AD4' and 'AD5' immediately under the PG20 record for the same Entity.

Note 2: Required if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides FDA with data about an Individual Point of Contact (POC) related to the Entity (the party) in the **preceding** PG19 record. Included in this record are the Individual Name, Telephone Number and Email address. A typical example is a POC for the Filer.

For each FDA entry line, at least one PG21 is required with the individual qualifier "FD1" (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier "PK" which should be the point of contact for the filer/broker. "PK" may be sent in one of the following ways:

- under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer) *FDA preferred method
- or as a secondary PG21 to FD1 using individual qualifier "PK" (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), or
- under any other required PG19 entity as long as "PK" is the individual qualifier in PG21.

If provided, there should be only one PK per entry line.

Although the PK (filer contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record to obtain the contact information for the filer. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only FD1 and PK are allowed.	1
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code 'INA'.	
Telephone Number of the Individual	15X	31-45	M	For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email address of the individual. If the Email Address needs more space, continue in a PG60 record with Qualifier Code 'EMA'.	

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication.

Record Identifier PG23 (Affirmation of Compliance)

This is a conditional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

If Medical Device then all Medical Device data is required, in addition to relevant radiation emitting product data elements. See also PG23 for Medical Devices.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. . See CBP's Appendix PGA, PG23 – Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes of ACE ABI CATAIR publication.	1
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. This could include a combination of letters and digits, specific text, etc. Follow the *Entered value of AoC Description / Business Rule* column in the table below in the Note section.	1
Filler	1X	80	C	Space fill	

Note 1

List of Affirmation of Compliance codes **CONDITIONAL** to FDA Radiation Emitting Product Message Sets

If 2877 is required:

Affirmation	**Qualifier**	**Examples and additional information**	**Additional Affirmations Required**	**Text on 2877**
RA1	date	format MM/YYYY	-	1.Were manufactured prior to the effective date of any applicable standard. Date of Manufacture:_____
RA2	text	text is reason for exclusion. Example: DOD exemption	-	2. Are excluded by the applicability clause or definition in the standard or by FDA written guidance. Specify reason for exclusion:_____
RA3	none			3. Are personal household goods of an individual entering the U.S. or being returned to a U.S. resident (Limit: 3 of each product type)

Affirmation	Qualifier	Examples and additional information	Additional Affirmations Required	Text on 2877
RA4	none			4. Are property of a party residing outside the U.S. and will be returned to the owner after repair or servicing.
RA5	text	text is description of the end product. Example: Laser Diode		5. Are components or subassemblies to be used in manufacturing or as replacement parts
RA6	none			6. Are prototypes intended for ongoing product development by the importing firms, are labeled "FOR TEST/EVALUATION ONLY" and will be exported, destroyed, or held for future testing.- there is a quantity limit for this option-stated on the back of the 2877 (page 2)
RA7	text	text is description of the end product		7.Are being reprocessed in accordance with P.L. 104-134 or other FDA guidance, are labeled "FOR EXPORT ONLY" and will not be sold, distributed or transferred without FDA approval.
RB1	none		If RB1 is entered then either ACC or ANC is required.	B1.Comply with the performance standards-1.*Last annual report or Product/Initial Report*
RB2	text	text is reason the product complies		B2.Comply with the performance standards-2. *Unknown manufacturer/report number. State reason:*
RC1±	none			C1.Do not comply with performance standards; are being held under a temporary import bond; will not be introduced into commerce, will be used under a radiation protection plan, and will be destroyed or exported under U.S. Customs Supervision when the mission is complete - 1. *Research , Investigations/Studies, or Training (Attach Form FDA 766)*
RC2	text	text is dates and use restriction	-	C2.Do not comply with performance standards; are being held under a temporary import bond; will not be introduced into commerce, will be used under a radiation protection plan, and will be destroyed or exported under U.S. Customs Supervision when the mission is complete - 1. *Trade Show/Demonstration; List dates and use restrictions*
RD1±	none			D1. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition.(See Form FDA 766) -1. *Approved Petition is attached.*

Affirmation	Qualifier	Examples and additional information	Additional Affirmations Required	Text on 2877
RD2±	none			D2. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition.(See Form FDA 766) - *2.Petition request is attached.*
RD3	date	date is the date form 766 will be provided, due within 60 days of submission.	-	D3. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition.(See Form FDA 766) - *3.Request will be submitted within 60 days.*
ACC	Product Report accession number	Syntax: 7 or 11 characters long Format: nnXnnnn-nnn where n is a 1-digit number and X is either a letter or a 1-digit number; '-nnn' is the optional Supplement Number.	If ACC is entered then RB1 is required	
ANC	Annual Report accession number	Syntax: 7 or 11 characters long Format: nnXnnnn-nnn where n is a 1-digit number and X is either a letter or a 1-digit number; '-nnn' is the optional Supplement Number.	If ANC is entered then RB1 is required	

±Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

List of Affirmation of Compliance codes **OPTIONAL** to FDA Radiation Emitting Product Message Sets

Affirmation	Qualifier	Examples and additional information	Additional Affirmations Required	Remarks
MDL	Text	Model Number of the Product	-	
ERR	Text	Entry Review Requested		Indicator Only. No data will follow.

Affirmation	Qualifier	Examples and additional information	Additional Affirmations Required	Remarks
IFE	Text	Import For Export		Indicator only. No data will follow
CCM	Text	Name of the Certified Component Manufacturer	-	EPRC Certified Component Manufacturer - in the diagnostic x-ray systems and their major components performance standard, manufacturers of major components are required to certify such components, which can be assembled by others into the finished x-ray system. In cases where the certifying component manufacturer is different from the manufacturer who is shipping the entire system to the U.S., this Affirmation of Compliance may be used to provide additional identifying information about that component manufacturer.

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be GEN.

If GEN, the PG24 is applicable to the preceding PG02. Only one PG24:GEN is allowed per PG02 (this is to avoid multiple PG24:GEN records without a guaranteed sequencing as intended by the filer).

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”24”	
Remarks Type Code	3X	5-7	O	FDA uses only GEN as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Record Identifier PG25 (Product Condition)

This is an optional PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers. If opting to transmit line value, MUST be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	Optional F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	Optional. If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Optional. Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Optional. Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier	1AN	15	O	Code of the entity that assigned the Lot number. 1 = Manufacturer Should not be entered if more than one PG25 record is entered	
Lot Number	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
Production Start date of the Lot	8N	41-48	O	Optional. The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	Optional. The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays while the missing information is obtained. If entered: The value associated with the PGA line number is in whole dollars. Should be entered only in the first PG25 record in the case of multiple PG25 records. If entered,	

				must be right-justified with preceding zeros and be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied. IF Import For Export (PG01) submitted THEN PG25 Value is MANDATORY	

Record Identifier PG26 (Product Packaging)

This is a conditional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity, Unit of Measure, Package Identifier, Packaging Method, Package Material, and Packaging Filler. Applies only for products subject to 2877 otherwise it is optional. If opting to transmit PG26, Packaging Qualifier, Unit of Measure, and Quantity must all be transmitted in accordance with the following instructions:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container and be a code from the table of base units listed below.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present. The same unit of measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	C	Although quantity is optional for non-2877 products, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays while the missing information is obtained. Quantity is conditional for 2877 products. If entered, this is the total quantity for the packaging level. Must be greater than zero. Two decimal places are implied. The base quantity must always be the last quantity transmitted. Entering Quantity shall require entering Packaging Qualifier and the Unit of Measure.	2,4
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX. At least, 'Pieces' must be selected. Cannot be repeated among the PG26 records.	3,4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA-Radiation-Emitting Products Message Sets:

Valid FDA Units of Measure for Packaging **Containers**

Code	***Description***
CS	Case
CT	Carton
BX	Box
PK	Package

Valid FDA Units of Measure for the **Base Unit** (Last Quantity Transmitted)

Code	***Description***
PCS	Pieces (Count)

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

950	Microwave Ovens	24,935.00 POUNDS
	Units 1-Quantity	950
	Units 1-Measure	PCS

Record Identifier PG27 (Container Information)

This is an optionalPGA input record that provides data pertaining to the shipping Container Number. The Number of the shipping container is included in the Bill of Lading. Hence this record is not needed. This record may be repeated.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“27”	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill of Lading.	
Container Number (Equipment ID)	20AN	28-47	O	The number of the shipping container as entered in the Bill of Lading.	
Container Number (Equipment ID)	20AN	51-70	O	The number of the shipping container as entered in the Bill of Lading.	

Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival/Entry Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is Mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Port of Arrival / Entry Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"30"	
Inspection/ Laboratory Testing Status	1A	5	M	A = Anticipated arrival information. If entry type = 21, then repeat PG30 and enter F = Foreign Trade Zone.	1
Anticipated Arrival / Entry date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	1
Anticipated Arrival/ Entry time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	1
Anticipated Arrival / Entry Location Code	4AN	18-21	O	Only a value of '2' (= Census Schedule D representing the CBP port codes) OR 4 (=FIRMS Code) is allowed.	
Anticipated Port of Arrival / Entry	50X	22-71	O	For valid port codes, refer to Note 1.	2
Filler	8X	72-80	M	Space fill	

Note 1:

For Non-PN shipments, A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms "port" and "port of entry" refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "ports of entry" within the meaning of these regulations).

Note 2:

Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“55”	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Record Identifier PG60 (Additional Information)

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”60”	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	72X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Note 1
Valid Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	**Description**
ENA	Entity Name for PG19
AD1	Entity address Line 1 for PG19
AD2	Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Entity City for PG20
INA	Individual Name for PG21
EMA	Email Address for PG21
TBN	Trade/Brand Name for PG07

PG60 record should follow immediately after its parent. For example, a PG60:ENA record should follow PG19 and a PG60:TBN record should follow PG07.

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping

In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Animal Drugs and Devices Commodity Data Elements and Values

Animal Drugs and Devices commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message.

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Animal Drugs and Devices	VME	Animal Drugs	ADR
FDA	Animal Drugs and Devices	VME	Animal Devices	ADE

Table 8 – Animal Drugs and Devices commodity hierarchy

The following are the potential PGA records associated with submitting Animal **Drugs** and Devices:

PG Record	Description
OI	The commercial description of the shipment
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	Product Identifier; the item type and Product Code detail are provided.
PG04	Product Constituent Active Ingredient
PG06	Product Source information is provided
PG07	The Trade/Brand Name
PG10	Product/Component Reporting Code
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1 are provided.
PG20	Additional Entity Identification (Address line 2, Apartment/Suite, City, State, and Zip/Postal Code).
PG21	Additional Entity Role
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Container Number
PG30	Product pertaining to the pertaining to the date, time and location of inspection; previous

PG Record	Description
	laboratory testing; inspection location; and anticipated arrival information for FDA
PG55	Additional roles performed by an entity or individual
PG60	Additional Information
PG00	Data Substitution

Animal Drugs and Devices Example

Animal Drugs and Devices Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.5 Example PG Message Sets.xlsx Tab:** ***Animal Drugs & Devices***

PGA Records and Data Elements required are dependent on the agency program and processing code selected. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message Set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"OI"	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, Amoxicillin	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, , Intended Use Code, Intended Use Description, and Disclaimer..

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"VME"	1, 2
Government Agency Processing Code	3AN	14-16	C	Codes allowed: ADR , ADE	1, 2
Intended Use Code	16X	42-57	C	See below for the list of New Intended Use Codes. Applicable only for Government Agency Processing Code ADR.	3
Intended Use Description	21X	58-78	O	N/A to FDA lines.	
Correction Indicator	1X	79	O	For future use	
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	

Note 1:
Refer to Table 8 above for commodity type and sub-type for Animal Drugs and Devices.

Note 2
If the product is to be disclaimed, then these data elements should both be populated with 'FDA'. Otherwise the Government Agency Program Code, Government Agency Processing Code are mandatory.

Note 3
The following Intended Use Codes are applicable only for Government Agency Processing Code ADR. The Intended Use Codes are not required for animal devices (Government Agency Processing Code: ADE

085.003		Drug subject of a new animal drug application, conditionally approved application, or Index listing
100.000		Importation for Personal Use
150.013		Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding
150.020		Active Pharmaceutical Ingredient / Bulk Drug Substance used to be further manufactured into a finished drug subject of a new animal drug application, conditionally approved application, or Index listing
180.009		For research and development in a pharmaceutical product – clinical investigations in animals (INAD)

180.018		For research and development in a pharmaceutical product – for tests in-vitro or in laboratory research animals.
920.000		US Goods Returned
970.000		Import for Export
980.000		For Other Use: (APIs or Finished Drugs not elsewhere classified)

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P).

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	"FDP".	
Product Code Number	19X	10-28	M	FDA Product Code must be exactly 7 characters	

Product Code Qualifiers and their descriptions can be found in CBP's Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Animal Drugs, this is currently always 'FDP' for all FDA products.

Only one FDA Product Code Number per line is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A: Alphabetic; AN: Alphanumeric

*** Edit to limit Industry Codes, dependent upon the Government Agency Program/Processing Codes ***

IF Government Agency Program Code = 'VME' and Government Agency Processing Code = 'ADE'
THEN PRODUCT.CODE.INDUSTRY = 68

IF Government Agency Program Code = 'VME' and Government Agency Processing Code = ADR
THEN PRODUCT.CODE.INDUSTRY = 56, 60, 61, 62, 63, 64, 65, 66, 67 or if (Industry_code = '54' and subclass _code is ('N', and 'R'))

Record Identifier PG04 (Product Constituent Element)

This is an optional PGA input record that provides data pertaining to Constituent Active Ingredient Qualifier, Name of the Constituent Element, Quantity of Constituent Element, Unit of Measure, and Percent of Constituent Element for the product identified by Product Code Number in PG02. This record can be repeated.

The PG04 record is not required IF Government Agency Program Code = VME AND Government Agency Processing Code = ADE; may be entered if Government Agency Program Code = VME AND Government Agency Processing Code = ADR.

Using a Drug example, Appendix C shows how PG04 can be used at the Product-level for multiple Constituent Elements. The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time.

Record Identifier PG04 (Product Constituent Element)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"04"	
Constituent Active Ingredient Qualifier	1A	5	O	Active ingredient = "*Y*" if yes, blank if no.	1
Name of the Constituent Element	51X	6-56	O		1
Quantity of Constituent Element	12N	57-68	O	2 decimal places are implied	1
Unit of Measure (Constituent Element)	5AN	69-73	O		1
Percent of Constituent Element	7N	74-80	O	4 decimal places are implied	1, 2

Note 1
IF Government Agency Program Code = VME AND Government Agency Processing Code = ADR
THEN Constituent Active Ingredient Qualifier and Name of the Constituent Element are entered.
Either the quantity and Unit of Measurement are entered **OR** the Percent Constituent Element is entered.

May REPEAT PG04 for EACH Active Pharmaceutical Ingredient
Example1: Ibuprofen, 200mg tablets
Name of the Constituent Element = Ibuprofen
Quantity of Constituent Element = 200 and Unit of Measure = milligrams

Example2: Aluminum zirconium tetrachlorohydrex
Name of the Constituent Element = aluminum zirconium tetrachlorohydrex
Percent of Constituent Element 18.2% (entered as 0182000)

Note 2

Examples of Percentages:

1000000	=	100%
0990000	=	99%
0090000	=	9%

0009000	=	.9%
0000900	=	.09%
0000090	=	.009%
0000009	=	.0009%

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) - other than the CBP Country of Origin - for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix C shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time**.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG"	
Record Type	2N	3-4	M	"06"	
Source Type Code	3AN	5-7	M	Mandatory valid values are 30 (Country of Source) or 39 (Country of Production) is MANDATORY. 294 (Country of Refusal) if previously refused. There would be one PG06 with source type code of 30 or 39. If previously refused, then trade would also provide another PG06 with source type code 294.	**1**
Country Code	2X	8-9	M	Country of production or source is required for Animal Drugs.	2

Note 1

Source Type Codes and their descriptions can be found in CBP's Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from CBP's Appendix B (ISO Country and Currency Codes) in the ACE ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is a conditional PGA input record that provides FDA with data pertaining to Trade Name for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix C shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time**.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	“PG”	
Record Type	2N	3-4	M	“07”	
Trade Name/Brand Name	35X	5-39	O	Market, Trade, or Brand Name that describes the animal drug or device at each line level. If Trade/Brand Name requires additional space, continue in a PG60 record with Qualifier Code ‘TBN’.	

Record Identifier PG10 (Product Characteristics)

For Animal Drugs, this is a mandatory PGA input record that allows for importer to report the description of the product for the product identified by Product Code Number in PG02 at the line level to capture the information currently collected in multiple OI records.

Using a Drug example, Appendix C shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time.**

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“10”	
Commodity Characteristic Description	57X	24-80	M	Free form description, NOT product code description, of the item.. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Animal Drugs, this is a mandatory PGA input record requiring Entity Role, Entity Name, and Entity Address 1.

Entity Identification Code and Entity number are optional data elements, but they are listed as conditional because If opting to transmit Entity Identification Code then Entity Number must also be provided, and vice versa.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 16 (DUNS #) or 47 (FEI #). Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	C	The Entity Number of the Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. If Entity Name requires additional space, continue in a PG60 record with Qualifier Code 'ENA'. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. If Entity Address1 requires additional space, continue in a PG60 record with Qualifier Code 'AD1'. See validation criteria below.	2

Note 1

Entity Role Codes and their descriptions can be found in CBP's Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes **mandatory** to FDA Drugs Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods (Final producer for the final drug product). If the product is a bulk API, use "MF" as the Entity Role Code (rather than "GD – Producer of API); If the product is in finished form, provide MF of final product.
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party

§ Same Role Code cannot be entered more than once.

List of Entity Role codes **optional** to FDA Animal Drugs Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	GD	Producer (Producer of the API*)

*API – Active Pharmaceutical Ingredient

REPEAT GD for EACH Active Pharmaceutical Ingredient in the dosage form

List of Entity Role codes optional to FDA Animal Drugs and Devices Message Sets:

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact (Filer/Broker Contact Information)

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Animal Drugs Message Sets is below:

Data Element	***Code***	***Description***	***Length/ Class***
Entity Identification Codes	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA/CVM prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when there is additional address information for the entity..

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity. If Entity Address2 requires additional space, continue in a PG60 record with Qualifier Code ‘AD2’.	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	
Entity City	21X	42-62	M	City of the entity. If Entity City requires additional space, continue in a PG60 record with Qualifier Code ‘ECI’.	
Entity State/Province	3AN	63-65	C	State/Province of the entity.	2
Entity Country	2A	66-67	M	ISO Country Code.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	C	Space fills.	

Note 1: If the Entity requires more than 2 address lines, use the optional PG60 records with Qualifier Codes ‘AD3’, ‘AD4’ and ‘AD5’ immediately under the PG20 record for the same Entity.

Note 2: Required if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides point of contact information.

For each FDA entry line, at least one PG21 is required with the individual qualifier “FD1” (sent with the preceding PG19 and PG20 FD1 record).

FDA also highly encourages the transmission of PG21 with the individual qualifier “PK” which should be the point of contact for the filer/broker. “PK” may be sent in one of the following ways:

- under a PG19PK (transmitting PG19PK, PG20PK and PG21PK for the filer) *FDA preferred method
- or as a secondary PG21 to FD1 using individual qualifier “PK” (transmitting PG19FD1, PG20FD1, PG21FD1, and PG21PK for the filer), or
- under any other required PG19 entity as long as “PK” is the individual qualifier in PG21.

If provided, there should be only one PK per entry line.

Although the PK (filer/broker contact information) is optional, transmitting this information will enable FDA to expeditiously contact the filer, instead of contacting the Importer of Record. If only the Importer of Record PG21 is transmitted and PK is not, FDA processing may be delayed.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1- 2	M	“PG”	
Record Type	2N	3-4	M	“21”	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. Only “FD1” and “PK” are allowed.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, continue in a PG60 record with Qualifier Code ‘INA’.	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address for the Individual	35X	46-80	M	Email Address of the individual. If the Email Address needs more space, continue in a PG60 record with Qualifier Code ‘EMA’.	

Record Identifier PG23 (Affirmation of Compliance)

This is a conditional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. There must be at least one PG23 record with the AoC code of REG when filing animal drug. See CBP's Appendix PGA PG23 – Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes of ACE ABI CATAIR publication.	1
Affirmation of Compliance Qualifier	30X	10-39	C	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see CBP's Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) for valid codes related to certain specific Affirmation of Compliance codes.	
Filler	1X	80	M	Space fill	

Note 1

The FDA Affirmation of Compliance Codes and their descriptions are listed in the Appendix PGA (Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes) of ACE ABI CATAIR publication.

Affirmation of Compliances are NOT required for Animal Devices.

The list of AoC codes **conditional** to FDA Animal Drugs Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
	REG	Animal Drug Establishment Registration Number	9N	IF Government Agency Program Code = VME and Government Agency Processing Code = 'ADR' and the Intended Use Code = 085.003, 150.020, 150.013, or 980.000 THEN REG IS MANDATORY.
	VAN	Abbreviated New Animal Drug Application Number (ANADA)	6N	IF Government Agency Program Code = VME AND PROCESSING CODE IS ADR and the Intended Use Code = 085.003 or 150.020 THEN EITHER VNA or VAN is MANDATORY; If Government Agency Program Code = VME AND PROCESSING CODE is ADR and the Intended Use Code = 980.000,

Data Element	Code	Description	Syntax	Business Rules
				THEN EITHER VAN, VNA is OPTIONAL.
	VIN	Investigational New Animal Drug Number (INAD and JINAD)	6N	IF Government Agency Program Code = VME AND PROCESSING CODE IS ADR and the Intended Use Code = 180.009 THEN VIN is MANDATORY. If Government Agency Program Code = VME AND PROCESSING CODE is ADR and the Intended Use Code = 180.018, THEN VIN is OPTIONAL.
	VNA	New Animal Drug Application Number (NADA) [also includes conditionally approved animal drugs (CNADA), Type A Medicated Articles, Legally Marketed Unapproved New Animal Indexed Drugs for Minor Species (MIF)]	6N	IF Government Agency Program Code = VME AND PROCESSING CODE IS ADR and the Intended Use Code = 085.003 or 150.020 THEN EITHER VNA or VAN is MANDATORY; If Government Agency Program Code = VME AND PROCESSING CODE is ADR and the Intended Use Code = 980.000, THEN EITHER VAN, VNA is OPTIONAL.
	NDC	National Drug Code	10N	IF Government Agency Program Code = VME AND Government Agency Processing Code = ADR and the Intended Use Code = 085.003, 150.020, 150.013, OR 980.000, THEN NDC is MANDATORY

The list of AoC codes **optional** to FDA Animal Drugs Message Sets is below:

Data Element	Code	Description	Syntax	Business Rules
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow
	VFL	Medicated Feed License (MFL)	6N	IF Government Agency Program Code = VME AND Government Agency Processing Code = ADR and Intended Use Code = 085.003,or 980.000 THEN VFL is OPTIONAL.
	VFD	Veterinary Feed Directive	Indicator Only	IF Government Agency Program Code = VME AND Government Agency Processing Code = ADR and Intended Use Code = 085.003 or 980.000 THEN VFD is OPTIONAL

The table below shows which Affirmations of Compliance are Mandatory (M), Conditional (C), or Optional (O) based on the Intended Use Code/Import Scenario:

Intended Use (see PG01 for definitions)		Import Scenarios	Mandatory Affirmations	Conditional Affirmations	Optional Affirmations

Intended Use (see PG01 for definitions)		Import Scenarios	Mandatory Affirmations	Conditional Affirmations	Optional Affirmations
085.003		Drug subject of a new animal drug application, conditionally approved application, or Index listing	REG, NDC, and VAN, or VNA		VFL, VFD
100.000		Importation for Personal Use			
150.013		Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding	REG, NDC		
150.020		Active Pharmaceutical Ingredient / Bulk Drug Substance used to be further manufactured into a finished drug subject of a new animal drug application, conditionally approved application, or Index listing	REG, NDC, and VAN, or VNA		
180.009		For research and development in a pharmaceutical product – clinical investigations in animals (INAD)	VIN		
180.018		For research and development in a pharmaceutical product – for tests in-vitro or in laboratory research animals.			VIN
920.000		US Goods Returned			
970.000		Import for Export			
980.000		For Other Use: (APIs or Finished Drugs not elsewhere classified)	REG, NDC		VAN, VNA, VFL, VFD

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be GEN.

If GEN, the PG24 is applicable to the preceding PG02. Only one PG24:GEN is allowed per PG02 (this is to avoid multiple PG24:GEN records without a guaranteed sequencing as intended by the filer).

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”24”	
Remarks Type Code	3X	5-7	O	FDA uses only GEN as its valid value.	
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Record Identifier PG25 (Product Condition)

This is an optional PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers. If transmitted, the line value must be included on the first PG25 record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported. for quality control or preservation purposes. A= Ambient, F=Frozen R=Refrigerated/Chilled, D=Dry Ice H=Fresh, U=Uncontrolled P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A = product B = container C = conveyance	
Lot Number Qualifier	1AN	15	O	Code of the entity that assigned the Lot number. For Animal Drugs the only valid value is: 1 = Manufacturer Should not be entered if more than one PG25 record is entered	
Lot Number	25X	16-40	O	The lot number that the manufacturer/ producer/grower assigned to the product.	
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	O	Although Line Value is optional, transmitting the value will assist in reviewing the product in a timely manner. Failure to transmit the value may result in delays while the missing information is obtained. If entered: The value associated with the	

				PGA line number is in whole dollars. Should be entered only in the first PG25 record in the case of multiple PG25 records. If entered, must be right-justified with preceding zeros and be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

Record Identifier PG26 (Product Packaging)

This is an optional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity, Unit of Measure, Package Identifier, Packaging Method, Package Material, and Packaging Filler. If included, please adhere to the following rules:

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container and be a code from the table of base units listed below.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present. The same unit of measure cannot be used multiple times on the same PGA line.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	O	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	O	Although quantity is optional, transmitting the quantity accurately and following the rules below will assist in reviewing the product in a timely manner. Failure to transmit the quantity records may result in delays while the missing information is obtained. If entered, this is the total quantity for the packaging level. Must be greater than zero. Two decimal places are implied. The base quantity must always be the last quantity transmitted. Entering Quantity shall require entering Packaging Qualifier and the Unit of Measure	2,4
Unit of Measure (Packaging Level)	5X	18-22	O	Type of packaging / packaging level. For example, BX. Cannot be repeated among the PG26 records.	3,4

Note 1

This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as “fill” and two decimal places following the value.

Note 3
List of Unit of Measure codes applicable to FDA- Animal Drugs and Devices Message Sets
For a full list of applicable Unit of Measure codes and Base Unit Codes, please refer to Appendix D in this document.

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pairs may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:
100 Cartons, 24 Aspirin 100 tablets 325 mg

Units 1-Quantity	100
Units 1-Measure	CT
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	100
Units 3-Measure	TAB

In this case, the invoice description contains the strength of the aspirin tablets. The product quantity is listed using the "Tablets" quantity unit code.

Record Identifier PG30 (Anticipated Arrival Information and Port of Arrival / Entry)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival/entry information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival/Entry Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) status code, date and time of arrival is Mandatory. For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required.

Record Identifier PG30 (Port of Arrival / Entry Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“30”	
Inspection/ Laboratory Testing Status	1A	5	M	A = Anticipated arrival information. If entry type = 21, then repeat PG30 and enter F = Foreign Trade Zone.	1
Anticipated Arrival / Entry date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	1
Anticipated Arrival / Entry time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	1
Anticipated Arrival / Entry Location Code	4AN	18-21	O	Only a value of ‘2’ (= Census Schedule D representing the CBP port codes) OR 4 (=FIRMS Code) is allowed.	
Anticipated Port of Arrival / Entry	50X	22-71	O	For valid port codes, refer to Note 1.	2
Filler	8X	72-80	M	Space fill	

Note 1:

For Non-PN shipments, A= Anticipated Arrival Date and Time at the Anticipated Port of Entry.

Port of Entry:
19 CFR 101.1.
Port and port of entry. The terms “port” and “port of entry” refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms “port” and “port of entry” incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not “ports of entry” within the meaning of these regulations).

Note 2:

Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

Not supported by FDA at this time

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“55”	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Record Identifier PG60 (Additional Information)

This is an optional PGA input record used to provide additional information about data in the PG record that precedes it during the submission of a PGA record set.

This record can follow a PG07, PG19, PG20 or PG21 record, and can only be used to provide the additional information noted by the Additional Information Qualifier Code list.

This record may be repeated.

Record Identifier PG60 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	”PG”	
Record Type	2N	3-4	M	”60”	
Additional information qualifier code	3AN	5-7	C	Code indicating the type of additional information being provided	1
Additional Information	72X	8-80	C	Text of the additional information related to the additional reference qualifier code	

Note 1

Valid Additional Information Qualifier Codes applicable to FDA Message Set are:

Code	**Description**
ENA	Entity Name for PG19
AD1	Entity address Line 1 for PG19
AD2	Entity address Line 2 for PG20
AD3	Entity address Line 3 for PG20
AD4	Entity address Line 4 for PG20
AD5	Entity address Line 5 for PG20
ECI	Entity City for PG20
INA	Individual Name for PG21
EMA	Email Address for PG21
TBN	Trade/Brand Name for PG07

PG60 record should follow immediately after its parent. For example, a PG60:ENA record should follow PG19 and a PG60:TBN record should follow PG07.

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

PG00 Substitution Grouping

In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"00"	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Appendix A: Use of PG10 Record

Here is an example of how the PG10 record is used to capture the information currently collected in multiple OI records. A group of PG10-PG26 data can provide information on multiple variations of the product that was generally identified in the OI record:

```
OI        VARIOUS SOFT AND HARD CANDIES
PG01001FDAFDA
PG02PFDP 33LGT07A
...
PG10      SOFT CANDY KR CHERRY SOURS 6/8 OZ
...
PG01002FDAFDA
PG02PFDP 33LGT07A
...
PG10      SOFT CANDY CB GUMMI BEARS 24/6 OZ PEG
...
PG01003FDAFDA
PG02PFDP 33LGT07A
...
PG10      SOFT CANDY KR GUMMI BEARS 6/9 OZ
...
```

Appendix B: Food Facility Registration Exemption (FME)

Code	Description
A	Facility is out of business
B	Facility is a private residence (21 CFR 1.227(b)(2))
C	Facility is a restaurant (21 CFR 1.226(d); 1.227(b)(10))
D	Facility is a retail food establishment (21 CFR 1.226(c); 1.227(b)(11))
E	Facility is a non-processing fishing vessel (21 CFR 1.226(f)
F	Facility is a non-bottled drinking water collection and distribution establishment (21 CFR 1.227(b)(2))
K	Unable to determine the registration number of the manufacturer

Appendix C: Sample use of PG04 – Product Constituent Element

Using the non-prescription Drug, ***Popular Product*** with multiple APIs[§], the example below shows how PG04 can be used at the product-level for multiple constituent elements.

OI	Analgesic/Human OTC Drug	
PG01	001	(Line#)
PG02	60LBF01	(Product Code)
PG06	39 Philippines	(Source Country Name)
PG07	Popular Product	(Brand Name)
PG10	Non/Rx Combination Ingredient - Modified Release Hard Gelatin Capsules	
PG04	API1	(Constituent Element #1)
PG04	API2	(Constituent Element #2)
PG04	API3	(Constituent Element #3)
PG19		

[§] API = Active Pharmaceutical Ingredient

The above example shows how the records PG05-PG06-PG07-PG10 are used at the **Product level**.

The FDA will accept PG05-PG06-PG07-PG10 records only at the Product-level (when they are under a PG02) at this time.

Avoid including PG05-PG06-PG07-PG10 under a PG04. PG05-PG06-PG07-PG10 records follow immediately the PG02 ; before any PG04 records.

Appendix D: FDA Unit of Measurement Codes

Valid FDA Units of Measure for Packaging Containers

Code	Description
AE	Aerosol
AM	Ampoule, Non-Protected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottlecrate, Bottlerack
BD	Board
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected,Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylnd
BR	Bar
BS	Bottle, Non-Prot Bulbous
BT	Bolt
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BY	Board in Bndl/Bnch/Truss
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CB	Crate, Beer
CC	Churn
CE	Creel
CF	Coffer
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil
CO	Carboy, Non-Protected
CON	Container
CP	Carboy, Protected
CTR	Cartridge

Code	Description
CR	Crate
CS	Case
CT	Carton
CU	Cup
CV	Cover
CX	Can, Cylindrical
CY	Cylinder
CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected
DR	Drum
EN	Envelope
FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FP	Filmpack
FR	Frame
GB	Bottle, Gas
GI	Girders
GZ	Girders in Bndl/Bnch/Trus
HG	Hogshead
HR	Hamper
IN	Ingot
IZ	Ingots in Bundle/Bnch/Trs
JC	Jerrican, Rectangular
JG	Jug
JR	Jar
JT	Jutebag
JY	Jerrican, Cylindrical
KEG	Keg
KIT	Kit
LG	Log
LZ	Logs In Bundle/Bunch/Trus
MB	Bag, Multi-ply
MC	Crate, Milk
MS	Sack, Muitiwall
MT	Mat
MX	Matchbox
NE	Unpacked Or Unpackaged
NS	Nest
NT	Net
PA	Packet
PAL	Pallet
PC	Parcel
PG	Plate
PH	Pitcher
PI	Pipe
PK	Package/Pack

Code	Description
PL	Pail
PN	Plank
PO	Pouch
PT	Pot
PU	Tray or Tray Pack
PY	Plates in Bndl/Bnch/Truss
PZ	Planks or Pipes, Bnd/Bnch
RD	Rod
RG	Ring
RL	Reel
RO	Roll
RT	Rednet
RZ	Rods in Bundle/Buch/Truus
SA	Sack
SC	Crate, Shallow
SD	Spindle
SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet
SM	Sheetmetal
ST	Sheet
SU	Suitcase
SW	Shrinkwrapped
SZ	Sheets in Bndl/Bnch/Truss
SY	Syringe
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular
TN	Tin
TO	Tun
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial
VL	Bulk Liquid
VO	Bulk,Solid,Lg Particles
VP	Vacuum-packed
VQ	Bulk Liquified Gas
VR	Bulk,Solid,Granular Parti
VY	Bulk,Solid,Fine Particle
WB	Wickerbottle

Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	Description	Measure Type
KM2	1,000 Square Meters	Area
M2	Square Meters	Area
SFT	Square Feet	Area
SQI	Square Inches	Area
SYD	Square Yards	Area
DOZ	Dozen	Count
DPC	Dozen Pieces	Count
DPR	Dozen Pairs	Count
GR	Gross	Count
NO	Number	Count
PCS	Pieces	Count
PRS	Pairs	Count
BOL	Boluses	Dosage
CAP	Capsules	Dosage
SUP	Suppositories	Dosage
TAB	Tablets	Dosage
CM	Centimeters	Length
FT	Feet	Length
KM	Kilometers	Length
LNM	Linear Meters	Length
M	Meters	Length
YD	Yards	Length
BBL	Barrels (42 Gallons Ea)	Volume
CFT	Cubic Feet	Volume
CM3	Cubic Centimeters	Volume
CYD	Cubic Yards	Volume
FOZ	Ounces, fluid	Volume
GAL	Gallons (US)	Volume
KM3	1,000 Cubic Meters	Volume
L	Liters	Volume
M3	Cubic Meters	Volume
ML	Milliliters	Volume
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
CAR	Carats	Weight
CG	Centigrams	Weight
G	Grams	Weight
KG	Kilograms	Weight
LB	Pounds (avdp)	Weight
MCG	Micrograms	Weight

Code	Description	Measure Type
MG	Milligrams	Weight
OZ	Ounces, weight (avdp)	Weight
STN	Short Ton (2000 LB)	Weight
T	Metric Ton	Weight
TON	Long Ton (2240 LB)	Weight
TOZ	Ounces, Troy or Apoth	Weight
AU	Allergy Units (ml or tablet)	Dosage
BAU	Bioequivalent Allergy Units (ml or tablet)	Dosage
PNU	Protein Nitrogen Units	Dosage